

A Critical Review of Civil Liability of Medical Science Researchers in Iran

Ali Arefi Maskouni^{1*} 

¹Assistant Professor of Law Department, Faculty of Law and Theology, Kerman Shahid Bahonar University, Kerman, Iran.

Received: 2023 February 26

Revised: 2023 March 13

Accepted: 2023 March 15

Published online: 2023 June 10

***Corresponding author:**

Faculty of Law and Theology, Kerman
Shahid Bahonar University, Kerman,
Iran.

Email: arefi@uk.ac.ir

Citation:

Arefi Maskouni A. A Critical Review of
Civil Liability of Medical Science
Researchers in Iran. Strides Dev Med
Educ. 2023 June; 20(1):40-47.
doi:10.22062/sdme.2023.198380.1183

Abstract

Background: The importance of medical science development is well known to everyone, and conducting various studies is necessary to achieve this development. In the meantime, the occurrence of mistakes and failures in the process of conducting medical science research is inevitable. In such an atmosphere, the significance of the civil liability issue in medical science research becomes obvious, and since dealing with this area in private law has been neglected by the legislator, and this important matter needs particular laws, it requires legislation to recognize the legal foundations of that issue.

Objectives: The current research was conducted aiming to critically review the civil liability issue of medical science researchers.

Methods: The method used in this study was critical review. A review study helps us understand what we know at present in a specific scientific field.

Results: Relying on each of the jurisprudential principles based on whether the study is therapeutic or non-therapeutic, and clinical or non-clinical, can lead to a different outcome in assigning liability to the researcher. Also, although there are definite foundations for civil liability in the legal system of Iran, in the field of medical science research, we are encountering a void of definite and revised regulations and procedures.

Conclusion: In addition to recognizing the studies in medical sciences, it is also necessary to provide the possibility to induce the least legal challenges in therapeutic or non-therapeutic clinical studies on a human subject. Although there are civil liability foundations stemming from medical science research in Iranian law, unfortunately, no certain procedure and law are observed in this regard, and it is necessary for the legislator to resolve this serious void by approving appropriate regulations because due to the complexities in medical science subjects, the general principles of civil liability regulations cannot be a solution on its own.

Keywords: Civil Liability, Medical Science Research, Researcher's Liability, Jurisprudence, and Law

Background

Medical sciences have had increasing progress in their various fields in Iran over recent years, and this progress was not possible without widespread research in all fields related to these sciences (1).

Topics concerning the role of law in medical science research in Iran were clearly proposed for the first time by the formation of the National Ethics Committee on Medical Science Research in 1999, the approval of the bylaw of this committee, and then the approval of the Tehran Statement (Approved Codes for the Protection of Human Subjects in Medical Sciences Research) in the same committee in which the legal status of medical science research was specifically considered. In a previously conducted scientific study, the degree of attention to the subjects of medical ethics in medical science research among students of Tehran University of

Medical Sciences during the years 1994 to 1997 was investigated, the data of which denote insufficient attention to the subjects of medical ethics in the process of conducting studies (2)

One of the essential issues of private law in the present era is the civil liability issue in the area of newly emerging activities. Although medicine and its related sciences have an old history, one cannot deny that nowadays, the speed of development in this field of experimental sciences has increased and exposed it to changes to the extent that the present conditions cannot be regarded as the previous conditions. On the one hand, these developments have increased the risk propensity of workers in the field of medical sciences. On the other hand, because of technical complexities, the field of medical sciences remains unknown to most of those who use these services. Such conditions strongly provide the conditions for the

emergence of disputes between providers and users of medical science services.

The presence of a single procedure in dealing with disputes induced in medical science research is a need felt by researchers and officials relevant to these studies in recent years. Because of the absence of a single law that objectively enumerates researchers' obligations, they are located in an ambiguous atmosphere that can challenge their motivations for the increasing development of their work, and individuals who are willing to participate in medical science research are also reluctant to participate in such an ambiguous atmosphere. Providers of medical science research services have serious concerns about responding to possible mistakes in their studies. The concern of unjust force to compensate for the damages that, in their opinion, they were not at fault for their occurrence can disappoint researchers and decelerate the development of medical sciences. Therefore, the exact determination of civil liability limits in medical science research seems beneficial for both the providers of these studies and their users. The current research was conducted to investigate the civil liability sources of medical science research in Iranian law.

Objectives

The current research was conducted aiming to critically review the civil liability issue of medical science researchers.

Methods

The method used in this study was critical review. A review study helps us understand what we know at present in a specific scientific field (3). A review study aims not only to describe and summarize previous literature, but a good review study should also be analytical, critical, and prescriptive. A critical review expresses the pros and cons of research studies conducted in a specific scientific field. It aims to review the most important and relevant research studies conducted in that scientific field and critical discussion about them (4). In the present study, the published texts concerning the legal principles and foundations related to medical science research available in Iran were investigated through a critical view.

Inclusion Criteria

The first inclusion criterion included the selection of studies to examine legal issues in research in various

books and research, and the second criterion included the entrance of books and theses related to the research subject.

The articles presented in conferences, congregations, and reports, and also the lack of access to the articles' full texts were also considered exclusion criteria (Figure 1).

Results

The first part of the findings dealt with explaining the research topic from the perspective of existing texts, including the explanation of the civil liability concept and the classification of medical science research, and the second part dealt with legal and jurisprudential sources in medical science research.

• Definition of Research in Medical Sciences

"Investigation and research are practices aiming to generally recognize the general chemical, physiological, or psychological processes" (5).

"The boundary between research and medicine is not totally obvious because both often appear together, just like research designed and conducted to evaluate a drug or a therapy that gets out of the usual and standard mode and turns into an experiment. Here, the word medicine refers to any practice that is in itself helpful for the patient and is carried out only to promote a patient's health and recovery, and the aim is to provide an individual with a diagnosis, preventive measure, or treatment. On the contrary, research refers to an action performed to test a hypothesis or draw a conclusion. Research is often designed in an official protocol that has an objective and methods to achieve the objective (procedure)" (5).

When the objective of medical practices is to investigate the rate of effectiveness or safety of a new therapy, and the subject is a human being under clinical care and clinical operation, research and therapy seem to be able to appear together. Overall, in cases where there is a doubt about whether a medical action is a research or therapy, as a general rule, research (whether mere research or research combined with therapy) appears to be considered the basis because this rule is more efficient in preserving the human dignity and rights of the individuals engaged in the process of medical operations, and as soon as the doctor and other medical staff enter the research stage, the subjects will benefit from more legal support.

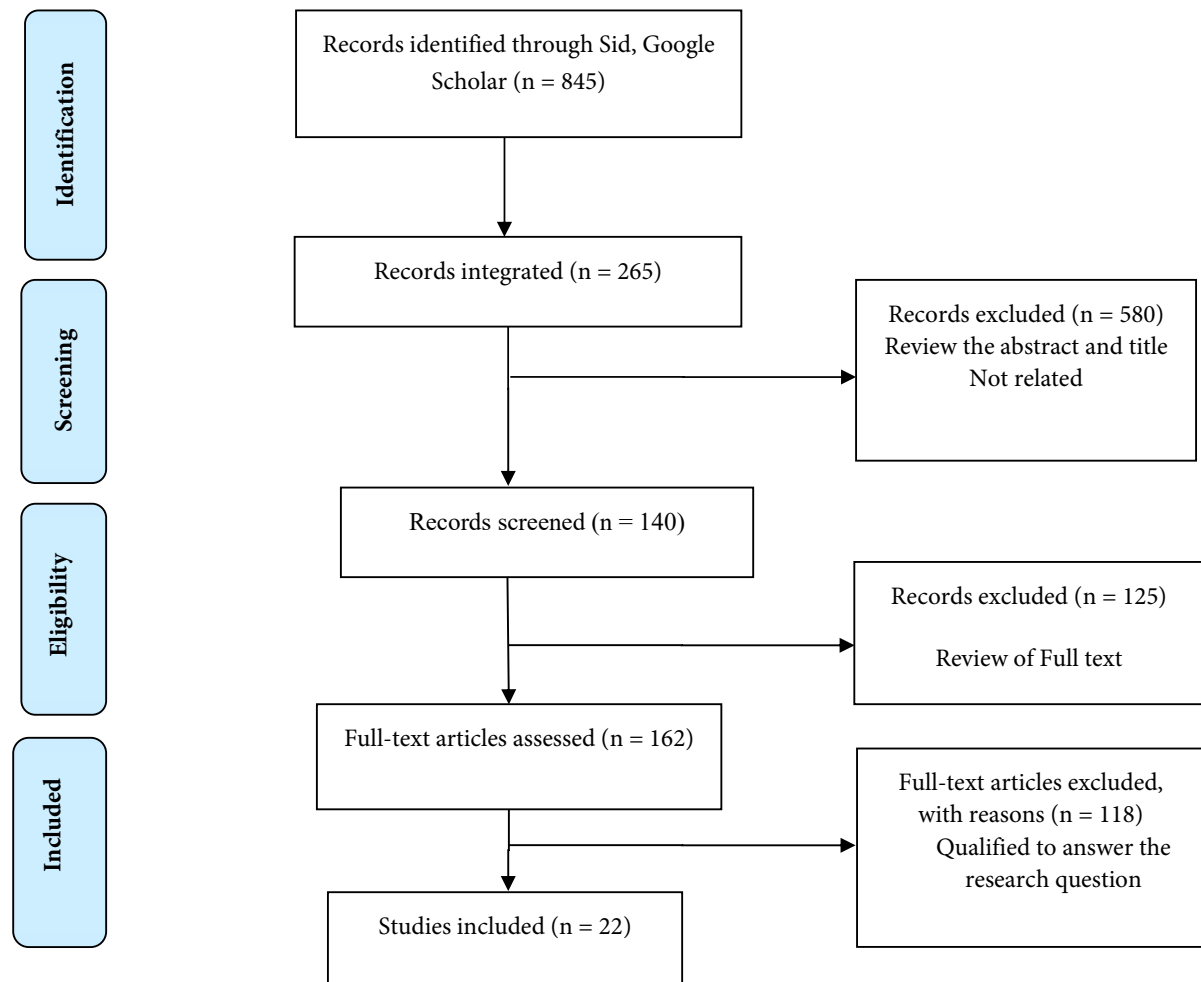


Figure 1: Screening diagram and selection of articles

It must be stressed once again that one cannot regard medicine and therapy as a form of research just because of deviating a doctor or medical staff from the usual path because, in such a case, the rights of patients and clients to receive medical services will be exposed to the risk of violation. Therefore, merely a type of innovation in the path of therapy should be regarded as research that has been foreseen in advance and has been approved by competent expert authorities, and concerning therapy-related research (therapeutic research), the possibility of treating the patient should also be reasonably included in conducting the research.

- **Classification of Medical Science Research**

An important point that should be considered regarding medical science research is that these types of research can also be different in practice in terms of civil liabilities depending on the diversity of their types. Thus,

the most important and common types of classification of such research are explained in the following.

A) Therapeutic and Non-therapeutic Research

If a conducted study while discovering new medical knowledge also seeks to treat a patient (the subject), it is called therapeutic research, and if it is not trying to treat the subject, it is called non-therapeutic research. Therapeutic research deals with examining a drug, treatment process, or diagnostic process on patients. Such research does not aim to benefit those who have undergone this trial, but the interests of patients who will be affected by the same disease in the future are intended" (6).

B) Clinical and Non-clinical Research

Another common classification is classifying medical science research into clinical and non-clinical. If the researcher has a subject case for his/her research and deals with conducting a field study on the effective

variables in his/her research for a subject, the research should be called clinical, and if he/she relies on library studies and reviews, then the research will be of a non-clinical type.

In the definition of clinical and non-clinical research, it can be said: "Regarding clinical research, a systematic categorization should be considered between clinical research whose aim is to treat the patient and clinical research whose topic is only scientific and has no therapeutic value for the human subject under research" (6).

Concerning non-clinical research, the condition is obviously different from other types of medical science research because when talking about non-clinical research, then conventional library method research and conducting various tests and during various foreseen stages, the results of all findings are used for human or non-human purposes.

C) Drug and Vaccine Production-Related Research

Considering the available procedures and laws governing conducting medical science research, this group of research should be evaluated clinically on human subjects in their final stages for final approval. It is evident that such research will finally be classified as clinical research. Of course, there is a difference between drug and vaccine-production-related research in terms of being therapeutic or non-therapeutic because the drug must be evaluated on the patient to measure its degree of efficiency and effectiveness, but the vaccine must be tested on individuals who are totally healthy, and in some cases, the history of the disease in question will even hinder the competence to participate in the vaccine test. From this perspective, drug-related research is therapeutic, and vaccine-related research is non-therapeutic (6).

D) Food and Nutrition-Related Research

In the field of medical sciences, there is always food and nutrition-related research as well. Since this group of research is not for treatment, they are certainly regarded as non-therapeutic. Now, if a human subject is investigated in the process of this group of research to obtain research results, that research should be classified as clinical research; otherwise, the mentioned research will naturally be of a non-clinical type (6).

The Civil Liability Concept

Civil liability has been created aiming at damage indemnification and compensation. Therefore, wherever someone is liable for compensating damage, civil liability is involved. In other words, civil liability is the manifestation of the relationship between the damage-causing person and the damaged person, which

often takes a financial form, and this relationship comes to an end with paying an amount as damage compensation (7).

Civil liability has been indeed created following damage compensation. In contrast, criminal liability is associated with punishment, and this punishment can be reforming the perpetrator or warning other society members, or the punishment may be enforced in defense of society. Civil liability and criminal liability have been previously merged. In many crimes, the punishment of someone who committed a crime was to pay damages to the damaged person himself/herself, as blood money (Dieh) in Islamic law has also the same meaning (8).

What is referred to as the damage must be certain and definite, and an individual cannot be condemned to pay possible damages; of course, it is sometimes difficult to calculate the precise amount of imposed damage, such as when the damage is related to the loss of physical ability for life, which does not remain as resorting to approximation and guessing a remedy to calculate the damage because the individual's rest of life or the amount of his/her usage of the lost ability for life cannot be accurately measured, or in the assumption that the occurred physical injury is a type of disease whose effects and consequences will expand over time at an unpredictable speed is also a similar situation.

From the perspective of the proponents of the theory of fault in civil liability, the induced loss must be predictable before its occurrence to the individual who has caused the damage. Of course, the proponents of the theory of fault in Iran's civil liability system acknowledge that the predictability that is a manifestation of the fault caused by the damage-causing person is not relevant in cases of pure liability (9).

Legal Sources in Medical Science Research

Civil Code

In Iran's Civil Code, regulations on tortious liabilities have been mentioned. This code has regarded tortious liabilities to be four causes, including usurpation and what has the force of usurpation, deliberate destruction, indirect destruction, and utilization. Out of these four topics, only deliberate and indirect destruction can be raised regarding medical science research, which, as stipulated by the Civil Code in Articles 328 and 331, these two topics are only relevant to belongings.

Therefore, deliberate and indirect destruction in Civil Code can only be used very limited in civil liability topics related to medical science research. In these articles of the Civil Code, the basis of civil liability tends to be strict liability or subjective liability. According to

the authors, “the Civil Code of fault-based liability has no priority over objective liability in this regard, and the weakness and strength of the causality relationship play a more important role in determining the liable person” (10).

Law of Tort

As acknowledged by some researchers, “In the law of tort, the legislator has considered fault to be the basis of liability and has regarded it as the principle” (9). Accordingly, if civil liability is considered in medical science research, it should be acknowledged that given the absence of specific laws in this field and the remaining law of tort, fault-based liability should be taken as the basis. However, the issue will not be solved so easily, at least regarding some examples of damages caused by medical science research. The law of tort, which is a general law in this field, has indeed not abolished the principles present in the Civil Code regarding indirect and deliberate destruction, which are considered specific to the law of tort, and these articles continue their legal life (10).

Islamic Penal Code

The Islamic Penal Code approved in 1991 had inconsistency in adopting the basis for doctor’s liability. On the other hand, in Articles 319 and 321, absolute liability and strict liability were accepted, while in Article 320, fault-based liability was raised (11). However, the Penal Code approved in 2013 followed a different procedure and by virtue of Article 495 and its note, “whenever a doctor causes physical loss or injury in his/her treatments, he/she is the blood money guarantor unless his/her action is in accordance with medical regulations and technical standards, or if he/she has obtained acquittal before the treatment and does not commit any fault, and if the acquittal of the patient is not valid because of his/her immaturity or insanity, or acquittal of the patient is not possible because of anesthesia, etc., the acquittal will be obtained from the patient’s guardian.”

In the Islamic Penal Code of 2013, the legislator moved a step from absolute liability to the theory of fault, and by adopting such a theory, although he has regarded the doctor’s liability as the document, he has allowed the doctor to be freed from the liability. The reason may be that adopting the basis of absolute liability for doctors challenges them in performing medical actions, and the fear of liability will be a barrier to providing medical services.

Adopting the procedure of the Islamic Penal Code of 2013 for medical science research, particularly research with a therapeutic aspect, will lead to the same problem in medical science research. If the theory of fault

assumption or statistics is followed in medical science research and one of the technical and specialized standards of therapy is considered rather than giving an effect as much as transferring the evidentiary burden of proof to the acquittal, the medical science research-related social interests will be considered better in the field of civil liability.

Jurisprudential Foundations of Civil Liability in the Field of Medical Science Research

Based on the famous opinion in Shi’a jurisprudence, “absolute liability” should be considered in civil liabilities. Therefore, in different types of civil liability or tortious liability, no place has been considered for the presence of a fault, and the damage-causing person has been regarded as liable absolutely (12, 13).

“Ghaedeh Lazarar”

The principle of harm is one of the most famous principles of jurisprudence, which is used in various cases. “The importance of the mentioned principle is to the extent that many jurists have devoted an independent treatise of their writings and interpretations to it since distant years” (14). Although different theories have been suggested by Shi’a jurists regarding the interpretation and domain of application of this principle, this principle can be considered the foundation of civil liability, which is completely consistent with absolute liability (15).

Accordingly, if the damage is caused concerning a research study (whether medical science research or otherwise), the civil liability of compensation will be with the damage-causing person, regardless of whether he/she has committed a fault in this regard or not. A point that should be taken into account is that in research, the researcher (whether a real or a legal person) is often engaged as an active agent in juridical fact. Therefore, in most damages, the researcher should be considered liable for damage compensation unless another agent interferes in causing the damage in such a way that it removes the causality between the researcher and the damage caused.

“Ghaedeh Etlaf”

The principle of deliberate destruction is an important and substantial principle in civil liability, which includes compensation for physical and financial damages (16). In the Civil Code of Iran, being a guarantor of an insane and a minor in compensating for the damages they have caused from their own belongings can be evidence of this claim that the principle of deliberate destruction involves absolute and strict liability. Also, if the researcher causes a loss of properties and bodies via conducting the research based

on the principle of deliberate destruction, the researcher's civil liability can be considered.

“Ghaedeh Zamane Yad”

Based on this principle, by creating domination over others' property, the liability of compensation, the benefits, and the same thing the possessor has possessed emerges. According to this principle, absolute liability has also been considered, and the fault does not contribute to knowing the possessor as liable (17).

The acceptance of the principle of liability of unlawful possession as the basis of the researcher's civil liability seems to be difficult because, as mentioned in the principle of liability of unlawful possession, creating domination over other's property is raised, and basically, this issue determines the border between the examples of this principle and the principle of deliberate destruction. In contrast, the researcher cannot have physical domination over the research subject (which in medical science research is human in many cases) to have physical dominance. On the other hand, this principle is often raised regarding property, and in medical science research, we are not dealing with property.

In response to this issue, perhaps today we can talk about the benefits of health or the benefits resulting from body organs as being property because even though limited and approximate, they can be calculated and valued, even if these things cannot be assigned or transferred. Furthermore, it should be said that the ownership and being the property in its different dimensions is a function of the custom of time and place. Therefore, customs may regard some medical science research subjects as property. However, it should be noted again that if we want to regard the principle of liability of unlawful possession as the basis, the research must be accompanied by domination over property, and if the research conducted by the medical science researcher has led to losing some interests of the subject, over which the researcher has not dominated in a particular sense, the issue will be among the examples of the principle of deliberate destruction.

“Zamane Ghoror”

Based on this principle, if an individual causes to deceive another individual with his/her behavior and, as a result of this deception, causes damage to a third party or if he/she himself/herself is damaged, it is the first individual who is considered liable for the damage caused. There are two assumptions regarding this principle. First, if the deceiver intends to deceive, which in this case, there is no disagreement on his/her being liable, but assuming that the deceiver does not intend to

deceive the person, some have rejected the possibility of knowing the deceiver as liable (15).

In any case, although the principle of liability against deception may be relied on and looked attentively in some assumption of damages caused regarding medical science research, the fact is that considering its limited scope that involves only cases of deception, this principle at least alone cannot be regarded as the basis of civil liability and cannot be considered in medical science research as in the first one.

The precision in the opinions collected in medical malpractice cases clarifies that the observance of scientific standards, the disease nature, the lack of a necessary relationship between the injury and medical measures, and the patient's negligence or fault are among the most important indicators that can contribute to the non-identification of the responsibility of medical service providers. Therefore, in the first place, observing scientific standards and making wise and conventional efforts can be effective in exonerating the doctor from liability. Based on this criterion, as much as the doctor is familiar with the state-of-the-art science, does not commit any fault, has sufficient precision in diagnosing the disease, and chooses an appropriate treatment method given the patient's condition, these are enough for the doctor to exonerate from liability. In the second place, some factors can be assumed as external factors beyond the medical service providers' will, and they are not involved in the realization or the emergence of that event. Therefore, if the event is unpredictable, unpreventable, or correctable, it will cut the causality relationship (18).

Discussion

Given the recognition of jurisprudence and legal foundations of the medical science researcher's liability, we can conclude that if the conducted research is of therapeutic type, we will encounter a phenomenon with different dimensions because the therapy and its resultant liabilities are separate issues. Also, although therapeutic research seeks to treat a subject's disease, one cannot deny that the predominance of research over therapy exists, and therapy is an outcome that should be obtained from research. In such a case, simply due to the presence of a therapeutic approach, it is impossible to regard the therapeutic liability of the doctors and medical staff as the basis for finding the person liable for compensating possible damages. On the other hand, it is not possible to leave the subject without legal support, and by resorting to foundations such as the jurisprudential principle of “assumption of risk: *velonti nonfit injuria*,” to rule that he is not entitled to claim damages because his/her action to

participate in the research is not the only cause of the assumed damage and other multiple and complex factors are also involved.

The different views and the lack of a specific law for medical science research can greatly enhance the risk of non-enforcement of justice in legal disputes stemming from liability in such research.

Numerous comments have been made regarding the civil liability of the medical science researcher. Although based on the theory of fault, the occurrence of fault by the researcher must be ascertained so that the researcher can be considered liable; based on the jurisprudential principle of harm, merely the association between the research activities and the damage caused suffices to regard the researcher as liable.

Depending on whether the research is therapeutic or non-therapeutic or clinical or non-clinical, relying on any of the jurisprudential principles can lead to different results in assigning liability to the researcher. Although there are definite foundations for civil liability in the legal system of Iran, in the field of medical science research, we are encountering a void of definite and revised regulations and procedures.

Conclusion

According to the present study's findings, although civil liability foundations stemming from medical science research are observed in Iranian law, unfortunately, there is no specific procedure and law in this regard. Therefore, it is suggested that the legislator eliminate the serious voids in this field by enacting appropriate regulations. Due to the complexities in general regulations concerning civil liability, these regulations should be stated more simply and practically, and special laws should be formulated in this area to provide legal support to medical science researchers.

Supplementary Material(s): is available here [To read supplementary materials, please refer to the journal website and open [PDF/HTML](#)].

Acknowledgements: We would like to thank the efforts of our dear colleague, Mr. Mohammad Reza Zangiabadi, for his collaboration in the stages of compiling this study.

Conflict of interests: The current research has not been submitted to other journals or publication sites and is not under review. The authors have no affiliation with any organization with direct or indirect financial interests in the topic discussed in this article.

Ethical approval: Not applicable.

Funding/Support: None.

Brief Definitions of Specialized Words

"Ghaedeh Lazarar": The principle of harm is one of the famous principles of jurisprudence that is used in most cases of jurisprudence, meaning that harm is not legitimate in Islam, and any harm and loss is negated in Islam.

"Ghaedeh Etlaf": The principle of deliberate destruction is one of the most famous jurisprudential principles, and jurists have used it extensively. The content of this principle is the same as the meaning of "he/she who causes a damage shall be liable for its compensation," meaning that "if someone destroys, consumes, or uses other's property without the permission of the property owner, he/she is a guarantor."

"Ghaedeh Zamane Yad": The content of this principle is that anyone who dominates over other's property, in any way unjustly, ignorantly, in trust, benevolently, becomes the guarantor of that property, and as long as he/she returns it to its owner, this liability does not fall from him/her.

"Zamane Ghoror": The lexical meaning of deception in Islamic jurisprudence is "a person damages another person due to his/her negligence and ignorance, in which case, the deceiving person is the guarantor of the damaged person."

References

1. Ashrafzadeh Farsangi M. (Dissertation). Patient's rights in the condition of doctor's acquittal from civil liability in Iranian law. Kerman: Shahid Bahonar University; 2014. [In Persian]
2. Smith T, Larijani B. Ethics in medical research. Tehran: Baraye Farda Pub; 2009. [In Persian]
3. Jesson J, Lacey F. How to do (or not to do) a critical literature review. *Pharmacy Education*. 2006; 6(2): 139-48. doi:10.1080/15602210600616218.
4. Saunders MN, Rojon C. On the attributes of a critical literature review. *Coaching: An International Journal of Theory, Research and Practice*. 2011; 4(2): 156-62. doi:10.1080/17521882.2011.596485.
5. Abbasi M. Medical Law and Responsibility in Islam. (Translation). Mubarak Al-Sh, Bin Mohammad Q. Tehran: Sina Legal Cultural Institute Pub; 2012. [In Persian]
6. Abbasi M. Collection of Ethics Codes in Research. Tehran: Sina Legal Cultural Institute Pub; 2013. [In Persian]
7. Khodabakhshi A. Basics and Concepts of Civil Responsibility. Tehran: Jungle Pub; 2013. [In Persian]
8. Katouzian N. Civil Rights Introductory Course: Civil Liability. Tehran: Publishing Company; 2015. [In Persian]
9. Bahrami Ahmadi H. Civil Liability (Civil Rights). Tehran: Mizan Legal Foundation Pub; 2019. [In Persian]
10. Katouzian N. Civil rights: non-contractual requirements (compulsory guarantee). Tehran: University of Tehran; 2018. [In Persian]
11. Safaei SH. Basis of Civil Liability of Physicians With A Glance at the New Bill for Islamic Penal Code. *Quarterly of Judicial Law Views*. 2012; 17(85): 141-56. [In Persian]

12. Mohseni F, Ansari R. Reciprocal impact of criminal responsibility And civil liability. *Journal of Legal Research*. 2019; 22(86): 353-81. doi: 10.29252/LAWRESEARCH.22.86.353. [In Persian]
13. Salehi SM, Faramarzi Razini F, Ghasemzadeh N. Physician's liability and presumption of innocence based on Shiite jurists' opinions: a review study. *Iranian Journal of Medical Ethics and History of Medicine*. 2013; 6(3): 17-29. [In Persian]
14. Montazeri S, Sadr Tabatabai MA. Analysis of the reasons and principles of medical responsibility in light of the teachings of Jurisprudence. *Journal of Criminal Law Research*. 2018; 6(21): 197-226. doi:10.22054/jclr.2018.12556.1219. [In Persian]
15. Bahrami Ahmadi H. Compulsory guarantee of "civil responsibility": with a comparative study in jurisprudence of Islamic religions and legal systems. Tehran: Imam Sadiq University; 2014. [In Persian]
16. Ahmadi S, Meskar M, Nargesian M. Physician Responsibility from the Perspective of Islamic Jurisprudence in Iran. *J Babol Univ Med Sci* 2016; 18 (2) :64-8. doi: 10.22088/jbums.18.2.64. [In Persian]
17. Wafai A, Ferman Ashtiani Y. (2022) The Role of Iodine Guarantee in Islamic Jurisprudence and Jurisprudence. *Qonun Yar*. 2022;5(19): 224-39. [In Persian]
18. Javan Jafai Bojnordi A, moshirahmadi A, Asrari M. Analyzing Indicators of Physicians non Responsibility in Forensic Precedent. *Alborz University Medical Journal*. 2022; 11 (4) :457-68 . [In Persian]