A new clinical use of Ferumoxytol nanoparticles: an anti-biofilm treatment

NCT06110494

17-Dec-2021

Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE: 17-Dec-2021
TO: Bekir Karabucak
CC:

RE:
IRB PROTOCOL#: 828211
PROTOCOL TITLE: A new clinical use of Feraheme nanoparticles: an anti-biofilm treatment

SPONSOR: NO SPONSOR NUMBER
REVIEW BOARD: IRB #6

IRB CONTINUING REVIEW: NOTICE OF APPROVAL

Dear Dr. Karabucak,

The above referenced protocol was reviewed and re-approved by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 on 16-Dec-2021. This study has been determined to be eligible for expedited review category(ies) 5, 1, 3.

This approval is for the period 16-Dec-2021 to 15-Dec-2022.

The documents included with the application noted below are approved:
-HSERA Continuing Review, confirmation code: dfcejbgh, submitted 12/15/2021
ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

UNIVERSITY OF PENNSYLVANIA

RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	A new clinical use of Feraheme nanoparticles: an anti-biofilm treatment
Principal Investigator:	Dr. Bekir Karabucak Department of Endodontics School of Dental Medicine University of Pennsylvania 240 S. 40th Street Philadelphia, PA 19104-6033 215-898-4617 (office) 215-573-2148 (fax) Endodontic Clinic 215-898-6062 (main)
Emergency Contact 1:	Dr. Alaa Babeer (610) 674-8970 (cell)

Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, you will still receive treatment as needed. Please ask the study doctor and/or the research team about this form [[for the further assistance]] if you do not understand any of the medical terms.

What is the purpose of this research study?

The purpose of this study is to develop a better, more effective disinfection protocol against infections within the root canal system, subsequently, improve the success of root canal treatment. Identifying the antibacterial benefits of Feraheme/H2O2 irrigation is the goal of our experiment. Feraheme is an iron replacement product that have been used with much higher concentrations in medicine as injections to improve and heal patients with iron deficiency. Feraheme used in this experiment is limited within the root canal system and applied on the tooth surfaces only. It will not be used systemically. this agent is not approved for the study's indications.

How long will I be in the study? How many other people will be in the study?

Your participation in this study will not require any more time than actually needed for the routine root canal treatment. We will be collecting information related to the diagnosis, chart number and tooth number. No protected health information such as name, address, telephone number, date of birth, social security number, personal and family medical history or results from physical examinations, tests or procedures will be used or collected

There are no additional procedures, questionnaires, or surveys required. We will have about 60 people participating in our study.

What are the possible risks or discomforts?

Only the risks or discomforts that can arise during or after any routine root canal treatment procedure apply. There are no potential risks expected from the noninvasive washing and sampling procedures, including any potential physical, psychological, social, economic, monetary, legal or other risks. Identifying the antibacterial benefits of Feraheme/H2O2 irrigation is the goal of our experiment. Feraheme with much higher concentrations have been used in medicine as

injections in the veins to improve and heal patients with iron deficiency. Feraheme systemic injections has been associated with increased amounts of iron in the blood, Hypersensitivity reactions in patients with multiple drug allergies, in only 2% of the cases it has been associated with adverse reactions of diarrhea, nausea, dizziness, hypotension (lowering of blood pressure), constipation, and peripheral edema (accumulation of fluid in upper and lower limbs). Feraheme used in this experiment is going to be 340 times less than the dose used systemically and it is limited within the root canal system and applied on tooth surfaces only. It will not be used systemically. Solution will be kept within the root canal system for a couple of minutes proposed in this protocol and will be evacuated by sterile saline, dental suction and paper points. Experiment was designed that the final root canal disinfection is not relying on experimental solutions antibacterial effect only. After bacterial sampling, the routine root canal treatment will be continued as needed. Besides tooth number, diagnosis and the PDM chart number (for potential verification of study correctness) no patient data will be collected by the Principle investigator. All treatment procedures at The University of Pennsylvania School of Dental Medicine, including the routine root canal treatment of the participants, during which the samples will be taken, are subject to strict HIPPA (privacy) and OSHA (hygiene) regulations. Your participation in this study will not require any more time than actually needed for the routine root canal treatment

What are the possible benefits of the study?

You are not expected to gain any benefit from taking part in this research study. The proposed study will verify by the means of microbial sampling and culturing, whether Feraheme/H2O2 irrigation protocol can provide better, effective disinfection on root canal surfaces and a significant reduction of infection inside the root canal. If this can be demonstrated by the proposed investigation it will have clinical significance as an improvement of root canal therapy

What other choices do I have if I do not participate?

If they do not wish to participate, you will not receive any treatment that is subpar as opposed to if they did agree to participate. If at any point, you decide you no longer want to participate, you will be excused from the study and will continue treatment as needed.

Will I be paid for being in this study?

There will be no compensation provided for taking part in this study.

Will I have to pay for anything?

There is no additional cost for you or your insurance company associated with our study.

When is the study over? Can I leave the Study before it ends?

This study is expected to end after a sufficient number of people enroll in the project. Your involvement with the study ends when the root canal treatment appointment has ended. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

This study may also be stopped at any time by the Primary Investigator without your consent.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the

principal investigator listed in this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

What information about me may be collected, used or shared with others?

We will be collecting information related to the diagnosis, chart number and tooth number. No other protected health information such as name, address, telephone number, date of birth, social security number, personal and family medical history or results from physical examinations, tests or procedures will be used or collected.

The U.S Office of Human Research Protections may receive your information. All human research is subject to their oversight.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations

Why is my information being used?

The chart number will only be recorded for a possible future verification of the research data such as tooth number and diagnosis. your chart number is secured by a login and password only accessible to students, residents and faculty of the dental school

. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

Additional to your clinical doctor who is performing the root canal,
The following individuals may use or share your information for this research:

- Dr. Bekir Karabucak (principal investigator listed above)
- Dr. Alaa Babeer (emergency contact listed above)

Who, outside of the School of Dental Medicine, might receive my information?

The U.S Office of Human Research Protections may receive your information. All human research is subject to their oversight.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission

- As permitted by law

Your Personal Health Information will not be used or disclosed during your participation in this study. Besides tooth number, diagnosis and the Penn Dental Medicine chart number (for potential verification of study correctness) no patient data will be collected by the Principle Investigator. All treatment procedures at the University of Pennsylvania School of Dental Medicine, including the routine root canal treatment of the participants, during which the samples will be taken, are subject to strict HIPPA (privacy) and OSHA (hygiene) regulations

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

If you decide not to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

You will be given a copy of this Research Subject consent form & HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are agreeing to participate in this research study, and you are authorizing us to use your chart number tooth number and diagnosis as described above.

_____	_____	_____
Name of Subject (Print)	Signature of Subject	Date
_____	_____	_____
Name of Person Obtaining Consent	Signature	Date