Accuracy of diagnostic imaging techniques in patients with a suspected fracture-related infection

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46568

Source
ToetsingOnline

Brief title
Imaging of fracture-related infections

Condition

- Bacterial infectious disorders
- Bone and joint injuries
- Fractures

Synonym
fracture-related infection, implant infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fracture-related infection, MRI, PET, white blood cell scintigraphy

Outcome measures

Primary outcome

The diagnostic accuracy of all different imaging modalities for diagnosing fracture-related infections (sensitivity, specificity, positive predictive value and negative predictive value).

Secondary outcome

Secondary parameters:

- Scores of the EQ5D and SMFA questionnaires in order to assess the quality of life and physical performance of patients with fracture-related infections.

- Scores of the iMCQ and iPCQ questionnaires in order to assess the medical costs associated with fracture-related infections.

Study description

Background summary

Post-operative infections after fracture treatment are one of the most severe and challenging complications in trauma and orthopaedic surgery. The complete spectrum of infections (e.g. acute, chronic, superficial or deep, with or without bone involvement, with or without implants in situ) following surgical fixation of a closed or open fracture are referred to as *fracture-related infections* (FRI). The reported incidence of FRI generally varies between 2-4%, but may increase up to 45%, depending on the comorbidities (diabetes, vascular disease, smoking) and the extent of the injury (presence of contaminated open fractures, concomitant soft tissue injuries, need for emergency damage control surgery). Fracture-related infections result in multiple re-operations, long antibiotic treatment, immobilization, inability to work and restrictions to participate in social activities. The personal impact for a patient, suffering

from a FRI, is significant. The treatment of an FRI can take several months or even years.

A fast and accurate diagnosis of fracture related infection would aid in optimal clinical decision making for this condition. However, consensus about the best diagnostic imaging modality for diagnosing fracture related infections is lacking in our current practice (6). Commonly requested imaging modalities for bone infections are a conventional magnetic resonance imaging (MRI), white blood cell (WBC) and fluorodeoxyglucose positron emission tomography (FDG-PET). The aforementioned techniques all have their capabilities and limitations to discriminate bacterial infections from inflammatory response due to the traumatic soft tissue damage and/or fractures, soft tissue reaction induced by the operative treatment of the injuries, and foreign body reactions due to implant placements (7). However, there is no literature, nor a uniform agreement regarding the best imaging technique that should be used to (early) detect and determine the extent of FRI*s. We recently conducted a systematic review on the accuracy of diagnostic imaging modalities for FRI, but were hampered by limited literature, heterogeneous patient populations and outdated imaging techniques (8). A proper prospective and sufficiently powered trial that compares these different imaging techniques for diagnosing FRI*s has never been carried out. Because, we as applicants of this study (trauma surgeons, orthopedic surgeons, nuclear physician, radiologist) are closely involved in treating patients with fracture-related infecties, we took the effort to improve the knowledge about this condition by initiating this trial.

Study objective

The primary aim of our *Imaging of Fracture-related Infections trial (IFI trial)* is to assess the diagnostic accuracy of all commonly requested medical imaging techniques (WBC scintigraphy, FDG-PET/CT and MRI). The secondary aim is to establish whether there are factors such as recent surgery, use of antibiotics, patient comorbidities and/or in situ implants that influence the diagnostic accuracy of these imaging modalities. Secondary goals are also to determine the quality of life the medical costs that arise from fracture-related infections.

Study design

This study is a multicenter prospective cohort study. All patients, who will be included in the IFI trial, will undergo three imaging techniques, namely a WBC scintigraphy, an FDG-PET/CT and an MRI, in order to determine the most accurate imaging strategy for diagnosing fracture-related infections.

Study burden and risks

The extent of burden and risks for patients participating in the study is

considered to be low. All imaging techniques used in this study (leucocyte scintigraphy, FDG-PET and MRI) are well established diagnostic techniques worldwide.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients >= 18 years with a suspected fracture-related infection will be included after a signed informed consent. The clinical suspicion of a fracture-related infection is based on several (clinical) parameters as defined by the consensus group of the international Arbeitsgemeinschaft für Osteosynthesefragen (AO Foundation) (1). See protocol, number 4.2, page 13.

Exclusion criteria

- Patients < 18 years, pregnant or lactating women, patients with claustrophobia or known allergies for intravenous contrast agents will be excluded from this study.
- Patients with evident acute postoperative surgical site infections and who don*t need additional diagnostic imaging because the clinical diagnosis of infection could be made without any doubt on the physical examination (e.g. evident pus drainage from the wound or wound dehiscence with exposed implants) will be excluded from this study (1, 9). According to the current practice, these patients don*t need additional imaging, because a reoperation will be performed anyway.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64898.042.18