Imaging of Fracture-related Infections (IFI)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21936

Source
Nationaal Trial Register

Brief title
IFI-trial

Health condition

infection; osteomyelitis; trauma; fracture-related infections; implant infection; infected osteosynthesis

NL: infectie; osteomyelitis; trauma; fractuur-gerelateerde infecties, geïnfecteerd implantaat; geïnfecteerd osteosynthesemateriaal

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: fund initiator

Intervention

Outcome measures

Primary outcome

The diagnostic accuracy (sensitivity, specificity, positive predictive value and negative

predictive value) for WBC scintigraphy, FDG-PET/CT and MRI, in order to determine the most accurate imaging strategy for diagnosing fracture-related infections.

Secondary outcome

- Determining whether the accuracy of the different image modalities is influenced by patient related factors such as in situ metal implants (plates, screws and intramedullary nails), recent surgery, open wounds or concomitant antibiotic treatment.

- Determining which imaging modality provides the most valuable information to the surgeon for planning revision surgery such as the exact location of the infection, the extent of the infection or the presence of sequestra, cloacae, sinus tracts, intra-cortical or soft tissue abscesses.

- To assess the quality of life and physical performance of patients with suspected fracture-related infections by using validated patient reported outcome measures.

- To design an evidence-based, feasible and cost-effective diagnostic pathway for patients with suspected fracture-related infections.

Study description

Background summary

Rationale: Infections after traumatic injuries and subsequent fracture treatment have major impact on the patient’s personal life in terms of multiple re-operations, long-term antibiotic treatment, immobilization, inability to work and restrictions to participate in social activities. Unfortunately, there is no consensus about which diagnostic technique (WBC-scintigraphy, FDG-PET/CT or MRI) is most accurate in detecting or ruling out fracture-related infections. Accurate diagnosis of an infection is important for the clinical decision making in order to determine the optimal surgical strategy.

Primary objective: Determining the overall diagnostic performances of WBC scintigraphy, FDG-PET/CT and MRI in patients with suspected fracture-related infections and establish the most accurate imaging strategy for diagnosing (or excluding) fracture-related infections.

Study population: Patients who need additional diagnostic imaging, according to the standard of care, based on a clinical suspicion of an infection (e.g. infected non-union or chronic posttraumatic osteomyelitis) following surgical fracture treatment.

Study design: All patients included in this prospective cohort study will undergo three

imaging techniques, namely a WBC scintigraphy, an FDG-PET/CT, and an MRI, to determine the most accurate imaging strategy for diagnosing fracture-related infections. This study won't influence the standard of care for these patients.

Main study parameters/endpoints: The diagnostic accuracy of all different imaging modalities (sensitivity, specificity, positive predictive value and negative predictive value) will be calculated.

Study objective

Determining the overall diagnostic performances of WBC scintigraphy, FDG-PET/CT and MRI in trauma patients with suspected fracture-related infections and establish the most accurate imaging strategy for diagnosing (or excluding) fracture related infections.

Study design

Diagnostics:

T=0: WBC scintigraphy, FDG-PET/CT, MRI

The golden standard for the final diagnosis whether there is a fracture-related infection or not will be based on the result of at least 5 intra-operative sampled microbiology cultures or (in case of no surgery) the clinical presence or absence of infection as judged by a trauma or orthopaedic surgeon (treating physician) at 1 year follow-up.

Functional outcome:

- T=0, 3, 6, 12 months, 1.5, 2 years: EQ-5D, SMFA

Cost analysis:

- T=0, 3, 6, 12 months, 1.5, 2 years: iMTA PCQ and iMTA MCQ questionnaires

Intervention

All patients, who will be enrolled 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. The diagnostic accuracy of all three imaging modalities (WBC scintigraphy, FDG-PET/CT, and MRI) will be determined with as reference the golden standard for the final diagnosis of a fracture-related infection.The golden standard for the final diagnosis whether there is a fracture-related infection or not will be based on the result of at least 5 intra-operative sampled microbiology cultures or (in case of no surgery) the clinical presence or absence of infection as judged by a trauma or orthopaedic surgeon (treating physician) at 1 year follow-up.

Contacts

Public

Scientific

Eligibility criteria

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).

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. 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
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-09-2018
Application type:	First submission

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
NTR-new	NL7275
NTR-old	NTR7490
Other	METc UMCG : 2018/141

Study results

Summary results

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