Imaging of Fracture-related Infections (IFI)

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21936

Bron
Nationaal Trial Register

Verkorte titel
IFI-trial

Aandoening

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

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: fund initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019

Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7275
NTR-old	NTR7490
Ander register	METc UMCG : 2018/141

Resultaten

Samenvatting resultaten

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