Systemic absOrption of Locally AdministeRed antibiotics (SOLAR) from the fracture site in adults with an open fracture or fracture-related infection; a prospective cohort study

Gepubliceerd: 30-06-2021 Laatst bijgewerkt: 18-08-2022

The primary hypothesis is that local antibiotics are a safe treatment option in the prevention and treatment of fracture-related infections, achieving higher local concentrations without the potential adverse events associated with systemic...

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

Samenvatting

ID

NL-OMON22256

Bron
NTR

Verkorte titel
SOLAR

Aandoening

Fracture related infection; Open fracture

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Systemic concentration of the locally administered antibiotic

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The proportion of patients who develop a fracture-related infection (FRI) ranges from 1% for closed fractures (1-2%) to 30% in patients with a (Gustilo-Anderson type III open fracture. Treatment of open fractures involves perioperative antibiotic prophylaxis (PAP). Treatment of FRI includes debridement with or without implant removal, and antibiotic treatment. Antibiotics can be applied at the fracture or FRI site, using powder, beads, or coating of fixation materials. Local administration of antibiotics is aimed at achieving higher local concentrations than can be achieved following systemic administration. Gentamicin is the most commonly used antibiotic. Adverse effects at too high concentrations include (reversible) nephrotoxicity and ototoxicity. Whereas studies have shown the local concentration to surpass this toxic concentration by far, data concerning their absorption in the systemic circulation in humans is scarce. This study is aimed to provide such data.
Objective: The primary aim of this study is to assess the absorption pattern of locally administered antibiotics into the systemic circulation in adult patients with an open fracture or a fracture-related infection. The secondary aims are 1) to assess the (re)occurrence of antibiotic-related adverse events; and 2) to assess whether the systemic level of locally administered antibiotics could be related to the occurrence of fracture-related infections.
Study design: Prospective cohort study.
Study population: Adult patients (aged 16 years or older) in whom a local antibiotic is administered at the fracture site (in case of open fracture) or infection site (in case of FRI) as part of their open fracture or FRI management, respectively.
Main study parameters/endpoints: The primary outcome measure is the systemic concentration of the locally administered antibiotic. This will be routinely measured until the level is below the measurement threshold. The secondary outcome measures are the occurrence of antibiotic-related adverse events (nephrotoxicity), defined as an acute kidney injury (AKI) and subdivided according to glomerular filtration rate (GFR), and the (re)occurrence of FRI within 3 months of follow-up.

Doel van het onderzoek

The primary hypothesis is that local antibiotics are a safe treatment option in the prevention and treatment of fracture-related infections, achieving higher local concentrations without

the potential adverse events associated with systemic administration

Onderzoeksopzet

Antibiotic levels are measured at 6 hours, 24 hours, and 48 hours postoperatively. Should the antibiotic level not show a decline, the level is measured daily for a longer period, until the decline becomes evident. During admission, it is measured every 24 hours, after discharge it is measured weekly. After the decline in level is evident, the level is measured weekly until the concentration has dropped below the measurement threshold.

Onderzoeksproduct en/of interventie

Local administration of antibiotics at (infected) fracture site

Contactpersonen

Publiek

Erasmus MC, University Medical Center Rotterdam
Prof. M.H.J. Verhofstad

+31107031050

Wetenschappelijk

Erasmus MC, University Medical Center Rotterdam
Prof. M.H.J. Verhofstad

+31107031050

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Age 16 years or older
2) Local antibiotic administered as part of the treatment for open fracture or FRI
3) Written informed consent by patient or proxy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Simultaneous systemic administration of same antibiotic
2) Insufficient understanding of Dutch or English language
3) Expected problems with maintaining follow-up

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	30-06-2021
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Undecided

Ethische beoordeling

Positief advies

Datum:	30-06-2021
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	NL9577
Ander register	METC Erasmus MC : MEC-2021-0446

Resultaten

Samenvatting resultaten
None yet