Effects of a single denosumab injection on reduction of total contact cast treatment and consolidation of bonefractures caused by acute Charcotfoot in patients with diabetes mellitus (CHARCOT study)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21814

Source
NTR

Brief title
CHARCOT study

Health condition

DM
charcot foot
denosumab

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Time to cession of total contact cast duration in combination with radiological improvement of bone quality between denosumab and placebo treatment

Secondary outcome

- Prevention of footdeformation (plantar pressure measurements i

- Changes in volume and foot temparature of both feet -

- changes in clinical risk score

- changes in plasma markers of bone metabolism

Study description

Background summary

we will investigate whether a single dose of denosumab injection sc will have a beneficial effect compared to placebo on time in contact cast (duration), bone quality improvement (radiological) and foot form conservation in patients with acute charcot foot . Also improvement in clinical riskscore variables and plasma markers of bone turnover will be studied.

Study objective

single denosumab injection has a beneficial effect on shortening time in contact cast and foot form preservation in DM subjects with an acute charcot foot

Study design

0,3,6 and 9 months

Intervention

single denosumab injection 60mg vs placebo injection subcutaneous

Contacts

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Eligibility criteria

Inclusion criteria

-Radiologically proven Charcot foot (x ray,CT or MRI)

- Male/female gender

- Confirmed diagnosis of either type 1 or type 2 diabetes with neuropathy

Exclusion criteria

- Scheduled dental treatment (molar extraction) in the next year

- Not able to give informed consent

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-03-2017
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-03-2017
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	NL6265

Register	ID
NTR-old	NTR6439
Other	METC : 2016_235

Study results