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Intranasal calcitonin in the treatment of acute Charcot neuroosteoarthropathy: a randomized controlled trial

Submission date	Recruitment status	[ ] Prospectively registered
02/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/02/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Robert Bem

Contact details
Videnska 1958/9
Prague 4
Czech Republic
14021

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MZO00023001

Study information

Scientific Title

Study objectives
Intranasal calcitonin can be effective in the treatment of acute Charcot foot.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the local ethics committee, and all participants gave written informed consent.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Diabetic Foot

Interventions
Intranasal Calcitonin 200 IU + Calcium 1000 mg per day or Calcium 1000 mg per day in monotherapy; two years follow-up period.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Calcitonin, calcium

Primary outcome measure
1. Effect on bone remodeling markers
2. Markers of disease activity - skin temperature

Secondary outcome measures
1. Prevention of deformities
2. Shortening of the treatment
3. Recurrence of Charcot foot

Overall study start date
01/08/2003

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Acute Charcot foot
2. Type 1 or Type 2 Diabetes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Foot ulcer
2. Acute osteomyelitis

Date of first enrolment
01/08/2003

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Czech Republic

Study participating centre

Videnska 1958/9
Prague 4
Czech Republic
14021

Sponsor information

Organisation
Institute for Clinical and Experimental Medicine (Czech Republic)

Sponsor details
Videnska 1958/9
Prague 4
Czech Republic
14021

Sponsor type
Industry

Website
http://www.ikem.cz

ROR
https://ror.org/036zr1b90

Funder(s)

Funder type
Research organisation

Funder Name
Institute for Clinical and Experimental Medicine MZO00023001 (Czech Republic)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration