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

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Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

- 1. Prevention of deformities
- 2. Shortening of the treatment
- 3. Recurrence of Charcot foot

Completion date

01/01/2007

Eligibility

Key inclusion criteria

- 1. Acute Charcot foot
- 2. Type 1 or Type 2 Diabetes

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration