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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

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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.

Primary study design
Interventional

Study design
Randomised controlled trial

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