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Oral bisphosphonate, alendronate, for the treatment of acute Charcot neuroarthropathy in diabetic patients

Submission date	Recruitment status	[ ] Prospectively registered
30/07/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/07/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2017	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4596

Study information

Scientific Title
Oral bisphosphonate, alendronate, for the treatment of acute Charcot neuroarthropathy in diabetic patients

Acronym
DRN144

Study objectives
Increased osteoclastic activity, resulting in osteopaenia, is a recognised feature of the pathogenesis of Charcot neuroarthropathy (CN); therapeutic agents which inhibit osteoclastic bone resorption should be efficacious in arresting the Charcot disease process. Our previously published study of the bisphosphonate pamidronate in this condition demonstrated improvement in symptoms and markers of bone turnover but no influence on disease activity. This necessitates the need for a larger randomised trial and with the availability of more potent oral bisphosphonates we propose to use the bisphosphonate alendronate in a randomised double-blind placebo-controlled trial. In active diabetic CN, we aim to confirm the hypothesis that bisphosphonates can modify disease activity and also influence the underlying pathogenesis of the condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 06/Q1407/74

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Both; Disease: Diabetic foot

Interventions

Alendronate

Follow-up length: 12 months

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Bisphosphonate (alendronate)

Primary outcome measure
Reduction in Charcot disease activity

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2008

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Type 1 or type 2 diabetes
2. Aged 18 - 85 years
3. Diabetic neuropathy
4. Active Charcot arthropathy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 78; UK sample size: 78

Key exclusion criteria

1. Peripheral vascular disease
2. Renal failure
3. Foot ulceration or celluitis or osteomyelitis
4. Previous amputation (more than midfoot)
5. Contraindication to study drug
6. Oesophageal or gastric problems (achalasia, ulcers)
7. Pregnancy
8. Breastfeeding
9. Risk factors for jaw osteonecrosis

Date of first enrolment
01/02/2008

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tameside General Hospital
Ashton-under-Lyne
United Kingdom
OL6 9RW

Sponsor information

Organisation
Tameside Hospital NHS Foundation Trust (UK)

Sponsor details
Tameside General Hospital
Fountain Street
Ashton-under-Lyne
England
United Kingdom
OL6 9RW

Sponsor type
Hospital/treatment centre

Website
http://www.tamesidehospital.nhs.uk/pages/default.asp

ROR
https://ror.org/04d713p41

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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