

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

Submission date 30/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/04/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

Reduction in Charcot disease activity

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Peripheral vascular disease
2. Renal failure
3. Foot ulceration or cellulitis 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

United Kingdom

England

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

Sponsor information

Organisation
Tameside Hospital NHS Foundation Trust (UK)

ROR
<https://ror.org/04d713p41>

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK)

Alternative Name(s)
The British Diabetic Association, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration