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Effect of treatment with an oral bisphosphonate on markers of bone formation and bone resorption in adults with alkpatonuria

Submission date	Recruitment status	[ ] Prospectively registered
27/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/02/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/02/2007	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
1

Study information

Scientific Title

Study objectives
With this explorative trial we will investigate the effect of treatment with a bisphosphonate on markers of bone formation and bone resorption in patients with this rare metabolic disorder.

Hypothesis:
Treatment with a bisphosphonate leads to a decrease in the level of the marker of bone resorption in a period of three months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Explorative trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Alkaptonuria

Interventions
Three months oral treatment with risendronate 5 mg per day

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Risendronate

Primary outcome measure
1. Change in bone markers
2. Bone formation: plasma alkaline phosphatase
3. Bone resorption: urine type I collagen cross-linked N-telopeptide

Secondary outcome measures
Pain using the Visual Analogue Scale (VAS)-score

Overall study start date
01/09/2005

Completion date
01/12/2005

Eligibility

Key inclusion criteria
1. Patients with alkaptonuria
2. Osteopenia or osteoporose on Dual Energy X-ray Absorptiometry (DEXA)-scan
3. Age minimally 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
6

Key exclusion criteria
1. Short life expectancy
2. Hepatic or renal disease
3. Excessive use of alcohol

Date of first enrolment
01/09/2005

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
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3584 CX

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details
Department of Internal Medicine
P.O. Box 85500
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Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Utrecht (UMCU) (The Netherlands)

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