

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

Submission date 27/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/02/2007	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

Contact name
Dr H W de Valk

Contact details
University Medical Centre Utrecht (UMCU)
Department of Internal Medicine
P.O. Box 85500
Heidelberglaan 100
Utrecht
Netherlands
3584 CX
+31 (0)30 250 8323
H.W.devalk@umcutrecht.nl

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Explorative trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Pain using the Visual Analogue Scale (VAS)-score

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

Netherlands

3584 CX

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University Medical Centre Utrecht (UMCU) (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration