

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28328

Source

NTR

Brief title

N/A

Health condition

Alkaptonuria.

Sponsors and support

Primary sponsor: UMC Utrecht

Source(s) of monetary or material Support: None (UMC)

Intervention

Outcome measures

Primary outcome

1. Change in bone markers;

2. Bone formation: Plasma alk. phosphatase;
3. Bone resorption: Urine Type I collagen cross-linked N-telopeptide.

Secondary outcome

Pain using the VAS-score.

Study description

Background summary

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

Study objective

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

Study design

N/A

Intervention

Three months oral treatment with risendronate 5 mg per day.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with alkaptonuria;
2. Osteopenia or osteoporose on DEXA-scan;
3. Age minimally 16 years.

Exclusion criteria

1. Short life expectancy;
2. Hepatic or renal disease;
3. Excessive use of alcohol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	6
Type:	Actual

Ethics review

Positive opinion	
Date:	02-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL391
NTR-old	NTR431
Other	: 1
ISRCTN	ISRCTN12672997

Study results

Summary results

N/A