A cross-over study to compare tolerability and efficacy of brand versus generic alenronate in postmenopausal women with osteoporosis.

No registrations found.

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

Summary

ID

NL-OMON26372

Source
NTR

Brief title
Generic study

Health condition

Postmenopausal Osteoporosis, tolerability, efficacy, Bisfosfonates
Osteoporose, tolerantie, werkzaamheid, bisfofonaten

Sponsors and support

Primary sponsor: Investigator initiated trial (IIT)
Source(s) of monetary or material Support: Investigator initiated trial (IIT)

Intervention

Outcome measures

Primary outcome

Vergelijken van tolerantie en effectiviteit (dmv van vragenlijsten en botmarkers) van specialite alendronate ten opzichte van generiek alendronate.

Secondary outcome

Geen.

Study description

Background summary

Study Title:

Comparison of tolerability and efficacy of brand versus generic alendronate.

Objectives:

Evaluation of difference in tolerability and efficacy as measured by bone markers between generic versus brand alendronate in postmenopausal women with osteoporosis.

Design and Outcomes:

A randomized single centre cross-over study to test the tolerability and efficacy of brand compared to generic alendronate in postmenopausal women with established osteoporosis. Tolerability is evaluated by the Gastrointestinal Symptom Rating Scale (GSRS) questionnaire. Medication use and adherence is evaluated by the Self-efficacy for Appropriate Medication Use (SEAMS) Questionnaire and the Brief Medication Questionnaire (BMQ). Efficacy is evaluated by the assessment of bone-markers.

Interventions and Duration:

After randomization, patients start with generic alendronate or brand oral alendronate once weekly in a single blinded, open label setting. After the first period of 12 weeks, there is a cross-over to branded and generic oral alendronate once weekly respectively. Evaluation of tolerability, adherence and efficacy is planned at week 6, 12, 18 and 24. After the study period of 24 weeks patients will continue treatment with the alendronate formulation they prefer, according to current practice.

Sample Size and Population:

30 postmenopausal women with osteoporosis defined as a DEXA T-score <-2,5 SD and/or ¡Ý 1

vertebral fracture.

Study objective

Evaluation of difference in tolerability and efficacy as measured by bonemarkers between generic versus brand alendronate in postmenopausal women with osteoporosis.

Study design

Na screeningsperiode van max 89 dagen (max 2 visits) behandelperiode: 24 weken met op week 12 cross-over; in totaal 2 visits.

Intervention

Lichamelijk onderzoek, interview, bloed en urine onderzoek, invullen vragenlijsten.

Contacts

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Eligibility criteria

Inclusion criteria

1. Postmenopausal women 50 yrs or >;

2. Diagnosed with osteoporosis as defined by: DEXA: T-score of-2.5 at lumbar spine or femoral neck os total hip, and or a vertebral fracture;

3. No treatment for osteoporosis in the 12 month before inclusion;

4. Ability to understand study procedures and to comply with them for the entire lenght of the study.

Exclusion criteria

1. Patients with prior teratment of osteoporosis (bisfofonates, testosterone, hormone replacement therapy(HRT) , selective estrogen receptor modulators (SERMs) or calcitonin);

2. Patients who are previously intolerant of bisfosfonates;

3. Patients with disorders of esophageal motility or in whom oral bisfosfonates are contraindicated;

4. A history of upper GI tract disorder other than esophageal motility disorder is not a reason for exclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2009
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	18-06-2009
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	NL1757
NTR-old	NTR1867
Other	Viecuri MC : 09-016
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A