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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26372

Bron
NTR

Verkorte titel
Generic study

Aandoening

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

Ondersteuning

Primaire sponsor: Investigator initiated trial (IIT)
Overige ondersteuning: Investigator initiated trial (IIT)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2009
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	18-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1757
NTR-old	NTR1867
Ander register	Viecuri MC : 09-016
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A