ISRCTN63118444 https://doi.org/10.1186/ISRCTN63118444

The effect of the natural mineral supplement Aquamin™ together with the short chain fructooligosaccaride Nutraflora® on bone health in post-menopausal women

Submission date
12/08/2009

Recruitment status
No longer recruiting

Registration date
02/10/2009

Overall study status
Completed

Last Edited
01/08/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Emeir Duffy

Contact details
University of Ulster
Coleraine Campus
Coleraine
United Kingdom
BT52 1SA
+44 (0)28 7032 3543
em.duffy@ulster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of the mineral supplement Aquamin™ together with the short chain fructooligosaccaride Nutraflora® on bone mineral density and bone turnover markers in post-menopausal women: a double-blind, randomised, placebo-controlled trial

Study objectives
Osteoporosis and low bone mass is becoming a major public health problem with post-menopausal women being at the highest risk. Osteoporosis is a disease characterised by low bone mineral density (BMD), where the structure of bone deteriorates, making it more susceptible to fractures, especially in the spine, hip and wrist. A recent animal study has shown the mineral supplement Aquamin™ to enhance bone mineral density. Furthermore, there is also evidence that short-chain fructooligosaccharide (Nutraflora®) supplementation enhances bone mineral density in rats. This study sets out to investigate the effect of supplementation of Aquamin™ together with the short chain fructooligosaccaride Nutraflora® on bone health using bone mineral density and bone turnover markers as indicators of bone health in post-menopausal women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the University of Ulster approved on the 21st July 2008 (ref: REC /08/0083)

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Each treatment is incorporated into chocolate chews and will be supplemented with 2 x chocolate flavoured chews. Individuals are supplemented per day for 2 years.
Treatment 1: Placebo (maltrodextrin)
Treatment 2: Aquamin™ (1800 mg/d) alone
Treatment 3: Aquamin™ (1800 mg/d) with Nutraflora® (3.6 g/d)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Aquamin™, Nutraflora®

Primary outcome measure
Bone mineral density: dual energy X-ray absorptiometry

Secondary outcome measures
1. Bone resorption and formation markers:
1.1. Serum CTx: ELISA
1.2. Urinary deoxypryridinoline cross-links: ELISA
1.3. Urinary CTx: ELISA
2. Serum intact osteocalcin: ELISA
3. Serum N-terminal midfragment OC: ELISA
4. Vitamin D: ELISA
5. Free calcium: ELISA
6. Parathyroid hormone: ELISA
7. Salivary Cortisol: ELISACalcium: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, UK)
8. Phosphate: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, UK)
9. Full Blood Profile: Sysmex full blood analyser
10. Electrolytes: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, UK)
11. Liver function:
11.1. Albumin: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, United)
11.2. Alanine transaminase: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, UK)
11.3. Gamma-glutamyltransferase: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, United)
11.4. Total bilirubin: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, United)
11.5. Alkaline Phosphatase: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, UK)
12. Total protein: Automated instrument (Instrumentation Laboratories UK Ltd, Warrington, UK)
13. Anthropometric measurements: height, weight, waist circumference, measured using standardised procedures
14. Blood pressure
15. Mean daily dietary intake (4-day diet diary)

16. Habitual dietary intake: Food Frequency Questionnaire
17. Exercise: Physical Activtiy Questionnaire
18. Sun Exposure: Questionnaire

Overall study start date
01/01/2009

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Apparently healthy post-menopausal female volunteers (defined as having no menstrual period, bleeding or spotting during 1 year prior to enrolment)
2. Aged 48 - 75 years old
3. Weight less than 136 kg (DEXA [dual energy x-ray absorptiometry] limit 136 kg)
4. Community dwelling and fully mobile, with hormone implants (if used) removed at least one year prior to randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3 x 100 per study arm (n = 300 in total)

Total final enrolment
300

Key exclusion criteria
1. Osteoporotic bone density (T-score less than -2.5)
2. Corticosteroid medications during the previous 6 months
3. History/presence of chronic renal, hepatic, gastrointestinal disease or traumatic lumbar compression fracture
4. Evidence of collapsed or focal vertebral sclerosis
5. Menopause before the age of 40 years
6. Bone diseases or other condition known to affect bone status
7. Treatment with specific therapy for osteoporosis
8. Uncontrolled hypertension or heart failure, renal calculi
9. Volunteers should not have used any prescribed medication known to affect bone status
10. Use of dietary supplements containing calcium and vitamin D three months prior to the study

Date of first enrolment
01/01/2009

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Ireland

Northern Ireland

United Kingdom

Study participating centre
University of Ulster
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
Marigot Ltd (Ireland)

Sponsor details
Strand Farm
Currabinny
Carrigaline
Ireland
Cork
+353 (0)21 437 8727
coriena.murphy@marigot.ie

Sponsor type
Industry

Website
http://www.marigot.ie

ROR
https://ror.org/05kmpn815

Funder(s)

Funder type
Industry

Funder Name
Marigot Ltd (Ireland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014		Yes	No
Other publications	Associations of long chain polyunsaturated fatty acids with bone mineral density and bone turnover	30/07/2022	01/08/2022	Yes	No