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Radon Balneology and Physical Activity for Osteoporosis Prevention

Submission date
14/01/2014

Recruitment status
No longer recruiting

Registration date
10/02/2014

Overall study status
Completed

Last Edited
02/11/2015

Condition category
Musculoskeletal Diseases

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

Plain English Summary
Background and study aims
Osteoporosis is a common condition characterized by decreased bone mass leading to increased fracture risk. The economic burden was estimated at 799 million in Austria for 2010 and could increase by 28 % to 1,025 million in 2025. Mountain hiking is a popular form of exercise in the alpine region and a cost effective treatment. Numerous studies have confirmed the effects of exercise programs on bone metabolism and inflammatory markers in postmenopausal women (a high risk group for osteoporosis). Studies have also shown that radon balneotherapy can help reduce pain for patients with degenerative spinal disease, rheumatoid arthritis and ankylosing spondylitis. The aim of the study is to assess whether a combination of exercise and radon balneotherapy works better than exercise only.

Who can participate?
Females and males aged between 50 and 65 who are fit enough to complete a hiking program and can complete German questionnaires.

What does the study involve?
Participants are randomly allocated to one of two groups: exercise and radon balneotherapy or exercise and non radon (dummy) balneotherapy.
Participants have a week long treatment, then 6 weeks off, then another 3 day treatment, and a follow up period of 240 days.
The first treatment includes five 3-4 hours guided GPS monitored mountain hiking tours with a minimum of 300 meters altitude difference per day, and five radon or placebo baths.
The second treatment includes two hiking tours plus two radon or placebo baths.
Participants have blood tests at the start and end of each treatment weeks and 6 months after the last treatment. They also fill in questionnaires each time.

What are the possible benefits and risks of participating?
Benefits are 9 days of free stay, meals and guided hiking tours in an Austrian resort area.
The risks are comparable to that of a standard touristic stay in the alpine regions including spa visits with low dose radon hyperthermia.

Where is the study run from?
Gastein resort area in Salzburg, Austria

When is the study starting and how long is it expected to run for?
The study started in Autumn 2009 and is expected to run until Autumn 2015

Who is funding the study?
Gastein Research Institute, Paracelsus Medical University Salzburg (Austria).

Who is the main contact?
Dr. Arnulf Hartl
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Study website
http://www.radonhealth.at

Contact information

Type(s)
Scientific

Contact name
Dr Arnulf Hartl

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
E1216/8-2010

Study information

Scientific Title
Gastein Radon Balneology and Physical Activity for Osteoporosis Prevention: a randomized, placebo controlled intervention study

Study hypothesis

Does a combined exercise, hyperthermia and radon balneology treatment have any impact on central biomarkers for bone remodeling in a study population at the risk age for developing osteoporosis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Salzburg Ethics Committee (Ethikkommission für das Bundesland Salzburg], 26 May 2010, ref: E1216/8-2010

Study design
Double blind randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Patient information can be found at: http://www.radonhealth.at/downloads/anmeldeblatt-und-informierte-einwilligung-v3.pdf

Condition
Osteporosis prevention

Interventions
Exercise +/- Radon balneotherapy

Study subjects are allocated by random into a radon group and placebo group Randomization will be computed in blocks of four with an equal treatment allocation ratio. Radon- or placebo thermal-water bath filling is blinded with a personalized digital ID card that provides tub filling with either radon thermal water or radon degassed thermal water (placebo) in an automatic process. In this double blind setting neither the participants nor the bath attendant have knowledge of the composition of the water.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Plasma levels of OPG for bone formation, RANKL for bone reabsorption and their ratio (OPG /RANKL) as a measure for the balance of bone metabolism

Forearm venous blood is collected from all participants at baseline (day 0, timepoint 1; T1), end of first treatment week (day 6, timepoint 2; T2), start and end of the brushup (day 60 and 63, timepoint 3; T3 and timepoint 4; T4) and 6 months after the last treatment (followup, day 240, timepoint 5; T5).

Questionnaires assessing somatic complaints (Beschwerdenliste, Zerssen, D. v., 1976. Die Beschwerden- Liste - Manual. Weinheim: Beltz Test GmbH) and Quality of Life (Quality of life questionnaire of the European foundation for osteoporosis 41; QUALEFFO 41) are handed out for completion on T 1, T2, T3, T4, T5 and days T1, T3, T5, respectively.

Secondary outcome measures
1. Plasma levels of Osteocalcin (OC), Osteopontin (OPN), Leptin, Parathyroid Hormone (PTH) and Adrenocorticotropic Hormone (ACTH)
2. Somatic complaints and self-reported health. Questionnaires assessing somatic complaints (Beschwerdenliste, Zerssen, D. v., 1976. Die Beschwerden- Liste - Manual. Weinheim: Beltz Test GmbH) and Quality of Life (Quality of life questionnaire of the European foundation for osteoporosis 41; QUALEFFO 41) are handed out for completion on T 1, T2, T3, T4, T5 and days T1, T3, T5, respectively.

Overall study start date
01/09/2010

Overall study end date
01/09/2014

Eligibility

Participant inclusion criteria
1. Eligible participants are working females and males aged between 50 and 65.
2. Physical ability to meet the demands of the exercise program (i.e. at least 300 m of altitude difference per day) and sufficient knowledge of German to complete the questionnaires.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
90

Participant exclusion criteria
1. Acute or chronic disturbances of the immune system
2. Hyperthyreosis

3. Cardiac arrhythmia
4. Renal insufficiency
5. Severe cardiovascular diseases
6. Acute infections or fever
7. Iritis
8. An acute attack of polyarthritis
9. Participants should not have used hormone replacement therapy or any other therapy affecting the bone metabolism during the last 12 months before enrollment.

Recruitment start date
01/09/2010

Recruitment end date
01/09/2014

Locations

Countries of recruitment
Austria

Study participating centre
Institute of Physiology and Pathophysiology
Salzburg
Austria
5020

Sponsor information

Organisation
Paracelsus Medical University Salzburg (Austria)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Forschungsfond des Forschungsinstituts Gastein (FOI-FFF) of the Gastein Research Institute, Paracelsus Medical University Salzburg (Austria)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/03/2015		Yes	No