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The impact of osteoporosis on jaw bones

Submission date
29/10/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
20/12/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis is a disease of the skeletal system characterised by decreased bone density and deterioration which results in decreased bone strength and increased risk of fractures. According to the WHO data it is the second most common pathology right after cardiovascular diseases, and osteoporosis-related fractures can be seen in every third woman and every fifth man older than 50. Fractures caused by osteoporosis are often a cause of disability which significantly decreases quality of life, and can even cause death. Therefore, early diagnostics, prevention and initiation of treatment are very important. However, the most used diagnostic method for osteoporosis - dual-energy X-ray absorptiometry (DXA) – is not available for a broad population and cannot be used as a screening method. Since postmenopausal women often visit the dentist, dental X-ray images could be used to evaluate their osteoporosis risk. Cone beam computed tomography (CBCT) today is considered the basic diagnostic method in dental implantology, and is also widely used in periodontology, maxillofacial surgery, and orthodontics. The number of diagnostics using this method is increasing worldwide. CBCT is three-dimensional, there is a better resolution of several jaw structures, and it indicates changes in the quality and quantity of cortical mandibular bone, which would be beneficial to select the women with increased osteoporosis risk.
Losing teeth causes residual ridge resorption, which is a chronic progressive and irreversible process, and the causes of it are still not fully understood. Residual ridge resorption is a significant factor which affects the prosthetic rehabilitation of toothless patients and their ability to adapt to their prosthesis as well as the doctor’s options to construct an optimal complete denture. Using dental implants helps to improve the stability and retention of the complete denture, resulting in improved quality of life for the patients, but it must be considered that the implantation also requires an adequate amount and quality of alveolar bone. There are several factors which affect the residual ridge resorption. The data from clinical studies regarding osteoporosis and its effect on residual ridge resorption are controversial. When CBCT is used it is possible to determine exact degree of residual ridge resorption and the quality of bone and its relation to the decreased bone mineral density (osteoporosis). The aims of this study are to detect if the quality and quantity of the jaw bones assessed using CBCT are influenced by general bone mineral density, and to evaluate if CBCT can be used to evaluate osteoporosis risk in postmenopausal women.

Who can participate?
Postmenopausal female patients aged 55-95 who wear complete dentures and are undergoing CBCT

What does the study involve?
Participants complete questionnaires to determine their general health condition. To determine bone mineral density, a DXA scan is performed. It is a simple, non-painful, X-ray-like procedure that makes it possible to determine the mineral density of the spine and the femur. The amount of radiation is low (obtained in the natural radiation within 1-2 days). In order to determine the amount and quality of jaw bone and if it is to justify the need (e.g. insertion of a planned dental implant), CBCT is performed. It is a simple, non-painful, X-ray-like procedure. The amount of radiation in this method is 10 times lower than that of the normal CT scan.

What are the possible benefits and risks of participating?
Participants will learn their bone density and receive a free CBCT x-ray examination to evaluate jaw bones and plan dental implants. Risks relate to radiation, but they are relatively low.

Where is the study run from?
Riga Stradiņš University Institute of Stomatology (Latvia)

When is the study starting and how long is it expected to run for?
September 2017 to August 2021

Who is funding the study?
European Regional Development Fund 1.1.1.2. Activity Post-doctoral Research Aid (The State Education Development Agency)

Who is the main contact?
Dr Anda Slaidina
anda.slaidina@rsu.lv

Contact information

Type(s)
Scientific

Contact name
Dr Anda Slaidina

Contact details
Dzirciema street 20
Riga
Latvia
LV-1083
+371 (0)67456043
anda.slaidina@rsu.lv

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nr.1.1.1.2/VIAA/1/16/139, Agreement No. 9.-14.5/257

Study information

Scientific Title
The impact of osteoporosis on jaw bones in postmenopausal women

Acronym
OJB

Study objectives
1. Cone beam computed tomography (CBCT) can be used to define the risk of osteoporosis of postmenopausal women
2. Edentulous jaws residual ridge resorption is affected by general bone mineral density
3. Changes of cortical and trabecular bone detected by CBCT in first cervical vertebra is affected by general bone mineral density
4. The quality of the edentulous jaws (amount of cortical and trabecular bone) is affected by general bone mineral density

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/10/2017, The Ethics Committee of Rīga Stradiņš University (RSU) (Rīga Stradiņš University - main building, Dzirciema street 16, Riga, Latvia LV-1083; Tel: +371 (0)67061596; Email: inga.benina@rsu.lv), approval Nr. 28 / 05.IO.2OI7

Study design
Single-centre observational cross-sectional case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Osteoporosis, residual ridge resorption, quality of the jawbones

Interventions
According to the aims of the study the following will be performed:
1. CBCT imaging (Imaging Science’s i-CAT Cone Beam 3-D Dental Imaging System) (this examination will be performed on patients with indications such as planned dental implantation, etc). CBCT imaging will be analysed using i-CAT Vision and Dolphin Imagining software (Riga

Stradiņš University Institute of Stomatology, Ltd.), to detect the quality and quantity of mandibular cortical bone, toothless jawbone quality (amount and proportion of cortical and trabecular bone) and quantity (volume of toothless jaw). Radiological density of first cervical vertebra will be determined.
2. Questionnaire (medical history, dietary habits)
3. Dual-energy X-ray absorptiometry (DEXA) examination (Lunar DEXA DPX-NT, GE Medical Systems- in cooperation with Riga 2. Hospital) to detect osteoporosis (general bone mineral density). Examination will be performed for the lumbar vertebrae (L2-L4) and both femoral necks (total hip mean)

All mentioned observations will be performed at the beginning (baseline) of the study. They will not be repeated.

Intervention Type
Other

Primary outcome(s)
Cone beam computed tomography CBCT imaging analysed using i-CAT Vision and Dolphin Imagining software, OnDemand3DDental, to detect:
1. Volume and density of mandible and maxillae
2. Computed tomography mandibular index (superior), which was the ratio of the inferior cortical width to the distance from the superior margin of the mental foramen to the inferior border of the mandible
3. Computed tomography mandibular index (inferior), which was the ratio of the inferior cortical width to the distance from the inferior margin of the mental foramen to the inferior border of the mandible
4. Computed tomography mental index, which was the inferior cortical width of the mandible
5. Computed tomography cortical index, which was the type of the inferior mandibular cortex (Type 1, 2 and 3) and computed tomography mandibular indexes
6. Cross-section area of the whole mandible, area of the trabecular and cortical bone was measured in region of the mandibular right lateral incisor, first premolar, first molar and second molar
All mentioned observations will be performed at the beginning (baseline) of the study. They will not be repeated.

Key secondary outcome(s))
Radiological density of first and second cervical vertebra measured using CBCT /OnDemand3DDental software at baseline

Completion date
31/08/2021

Eligibility

Key inclusion criteria
The study will include female patients of Riga Stradiņš University Institute of Stomatology who:
1. Undergo CBCT (cone beam computed tomography) diagnostics due to other indications
2. Have menopause
3. Age 55-95 years
4. Agrees to participate in the study
5. At least 5 years edentulous

6. At least 3 years wearing complete dentures
7. Receive prosthetic treatment in Institute of Stomatology (complete dentures)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
55 years

Upper age limit
95 years

Sex
Female

Total final enrolment
127

Key exclusion criteria
1. Patients with diseases and conditions leading to the secondary osteoporosis (kidney disease, hyperparathyroidism, Cushing syndrome, thyrotoxicosis, rheumatoid arthritis, organ transplantation, diabetes mellitus)
2. Women with early menopause (before age 45) or surgical menopause
3. Patients who use or have used a year prior to the study medications affecting bone metabolism (glucocorticoids, bisphosphonates, strontium ranelate, selective oestrogen receptor modulators, HRT, calcitonin, active metabolite of vitamin D, teriparatide, etc.) except those who use calcium less than 1000 mg or vitamin D less than 800 IU per day
4. Smokers
5. Excessive alcohol abusers (more than 14 alcohol units per week)

Date of first enrolment
01/10/2017

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
Latvia

Study participating centre

Riga Stradiņš University Institute of Stomatology
Dzirciema Street 20
Riga
Latvia
LV-1083

Sponsor information

Organisation
Riga Stradins University

ROR
https://ror.org/03nadks56

Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund 1.1.1.2. Activity Post-doctoral Research Aid (The State Education Development Agency)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Anda Slaidina (anda.slaidina@rsu.lv).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2022	04/10/2022	Yes	No
Results article		03/01/2023	20/12/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			04/10/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes