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Artificial intelligence-assisted osteoporosis risk assessment in jaw x-rays

Submission date
04/11/2024

Recruitment status
No longer recruiting

Registration date
12/11/2024

Overall study status
Completed

Last Edited
12/11/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Osteoporosis is a skeletal system disease characterised by decreased bone mineral density (BMD) and microarchitectural damage, resulting in decreased bone strength and a significantly increased risk of bone fracture. According to the WHO, osteoporosis is the second most common pathology after cardiovascular disease, and fractures occur in one in three women and one in five men over the age of 50 years old. Osteoporosis poses a huge personal and economic burden. Therefore, early diagnosis of osteoporosis and the initiation of prevention or treatment becomes important. However, the most widely used method of diagnosing osteoporosis today dual-energy x-ray absorptiometry (DXA) is not publically available and cannot be used as a screening method. As postmenopausal patients often visit the dentist, it has been hypothesised that dental radiographs could be used to determine the risk of osteoporosis. A previous study showed an altered mandibular cortical bone structure and thickness in postmenopausal women with reduced BMD. These changes could be easily and accurately detected on digital panoramic radiographs, therefore the presence of osteoporosis could be detected with high probability. Nowadays, panoramic imaging is performed less frequently because of the availability of inexpensive, three-dimensional, with reasonable radiation levels cone-beam computed tomography (CBCT). Today CBCT is used in dental implantology and widely used in periodontology, oral and maxillofacial surgery, orthodontics, etc. The number of examinations being performed is increasing worldwide. CBCT is more informative, as it is 3-dimensional and different jawbone structures are visible in high resolution. This suggests that changes in the quantity and quality of mandibular cortical bone detected by this examination could be even more accurate in detecting women at increased risk of osteoporosis. Previous studies have shown that women with reduced general BMD also have reduced cortical bone thickness in the mandible. However, more research is needed to determine the best mandibular areas for detecting osteoporosis-induced changes using CBCT scans. This study aims to develop an AI-based method for detecting osteoporosis risk in postmenopausal women by analyzing changes in mandibular cortical and trabecular bone. Additionally, it will assess the impact of osteoporosis on temporomandibular joint (TMJ) bone structures, providing essential knowledge for improving osteoporosis detection and potentially enabling mass screening.

Who can participate?
Postmenopausal female patients aged 55-95 years old who need to undergo a CBCT examination (e.g. due to dental implant planning)

What does the study involve?
Participants will complete questionnaires to determine their general health condition. To determine BMD, 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). To determine the amount and quality of the jawbone 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 a 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?
Rīgas Stradiņa Universitāte (Riga Stradiņš University [RSU]) Institute of Stomatology, Latvia

When is the study starting and how long is it expected to run for?
January 2022 to March 2026

Who is funding the study?
1. Latvijas Zinātnes Padome (Latvian Council of Science)
2. RSU Internal and RSU with LSPA External Consolidation (financed by the investment of the European Union's Recovery and Resilience Mechanism and the budget of the Republic of Latvia), No. RSU-ZG-2024/1-0010

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Additional identifiers

Protocol serial number
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Study information

Scientific Title
A deep learning approach for osteoporosis identification in postmenopausal women using cone-beam computed tomography

Study objectives
The first purpose of this interdisciplinary study is to develop a method for osteoporosis risk detection in postmenopausal women by assessing qualitative changes in mandibular cortical and trabecular bone on CBCT scans and to create a comprehensive deep-learning prototype model for osteoporosis risk detection.
The second purpose of this study is to assess the impact of osteoporosis in postmenopausal women on jawbones and temporomandibular joints (TMJ) bone structures (density, volume, surface structure of mandibular condyle).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 09/06/2022, Rīga Stradiņš University (RSU) Research Ethics Committee (Dzirciema 16, Riga, LV1007, Latvia; +37167061547; pek@rsu.lv), ref: 2-PĒK-4/336/2022

2. Approved 06/09/2024, Rīga Stradiņš University (RSU) Research Ethics Committee (Dzirciema 16, Riga, LV1007, Latvia; +37167061547; pek@rsu.lv), ref: 2-PĒK-4/552/2024

Primary study design
Observational

Study design
Single-center observational cross-sectional cohort study

Study type(s)
Diagnostic, Other, Screening

Health condition(s) or problem(s) studied
Detect the impact of osteoporosis on jawbone structures and develop a method to identify osteoporosis risk for postmenopausal women in the jawbone region.

Interventions
According to the aims of the study, the following will be performed:
1. Cone beam computed tomography (CBCT) examinations at the RSU Institute of Stomatology

with one device (i-CAT Next generation, KaVo Dental GmbH, Germany, Imaging Sciences International, Hatfield, PA) following one protocol developed by the institution for implant planning. The study will include only those patients who need to undergo a CBCT examination. All tests will be carried out with specific parameters: 120 kVp, 5 mA, 4 seconds, voxel size 0.3 mm, FOV size 230x115 mm. Patients requiring a lower FOV, e.g., patients for whom dental implants are planned in the mandible only, will be excluded from the study.
2. Dual-energy X-ray absorptiometry (DXA) examinations (Lunar DEXA DPX-NT, GE Medical Systems) will be performed on the lumbar vertebrae (L2-L4) and both femoral necks (total hip mean) to determine the bone mineral density [BMD]). All examinations will be performed by one experienced specialist (DXA).
3. Questionnaires: dietary parameters, medical history, temporomandibular disorder evaluation (RDC/TMD) The Axis I TMD Pain Screener
4. TMJ clinical examination (DC/TMD).

The CBCT images will be processed and analyzed with OnDemand3DTM software (Cybermed Inc, Seoul, Korea). In the Dental Module system. In the dental module system, three regions of the mandible will be selected in the axial view – the lateral incisor region (9 mm from the midline of the mandible), the first premolar region (6 mm anteriorly from the middle of the mental foramen), and the first molar region (6 mm distal from the middle of the mental foramen). A cross-sectional image will be obtained for each of these areas. The thickness, bone structure, and density (grey values) of the vestibular, lingual and basal cortical bone, bone structure will be determined in each region. The computed tomography cortical index (CTCI), which characterizes the structure of the mandibular cortical bone, will be determined: Type 1: the cortical endosteal margin appears even and tegular, Type 2: the endosteal margin shows semilunar defects or 1 to 2 layers of cortical endosteal residues; Type 3: the cortical layer has numerous endosteal residues and is clearly porous.

Measurements of the TMJ structures (shape, volume, density, structure, cortical bone thickness of condyle) will be undertaken in CBCT examinations.

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

Intervention Type
Other

Primary outcome(s)
The thickness, bone structure, and density (grey values) of the vestibular, lingual and basal cortical bone, bone structure will be measured at baseline and analyzed in each region using cone-beam computed tomography (CBCT) imaging with OnDemand3DTM software

Key secondary outcome(s)
Temporomandibular joints (TMJ) structures (shape, volume, density, structure, cortical bone thickness of condyle) will be measured at baseline and analyzed in each region using cone-beam computed tomography (CBCT) imaging with OnDemand3DTM software

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Reached menopause at least 1 year before the start of the study
2. Need a CBCT examination (e.g. for planning dental implants)

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
55 Years

Upper age limit
95 Years

Sex
Female

Key exclusion criteria
1. The study will not include patients with diseases or conditions that may cause secondary osteoporosis, such as kidney diseases, hyperparathyroidism, Cushing's syndrome, thyrotoxicosis, rheumatoid arthritis, etc
2. Women with early menopause before the age of 45 or surgically induced menopause were also excluded from the study
3. Patients who are taking and who one year before the study have taken medicines affecting bone metabolism such as glucocorticoids, bisphosphonates, strontium ranelate, selective oestrogen receptor modulators, HAT, calcitonin, active metabolites of vitamin D, teriparatide, etc., except calcium of less than 1,000 mg/day and vitamin D of less than 800 IU/day, were excluded from the study
4. Patients who smoked and/or abused alcohol (more than 14 units of alcohol per week) were also excluded from the study
5. Women with significant pathologies or inflammation in the jawbones
6. Women who had already undergone a DXA examination in the last year and had no indication of a DXA examination

Date of first enrolment
01/07/2022

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
Latvia

Study participating centre
Riga Stradins University Institute of Stomatology
Dzirciema 20
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Sponsor information

Organisation
Riga Stradiņš University

ROR
https://ror.org/03nadks56

Funder(s)

Funder type
Research council

Funder Name
Latvijas Zinātnes Padome

Alternative Name(s)
Latvian Council of Science

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Latvia

Funder Name
Rīgas Stradiņa Universitāte

Alternative Name(s)
Rīga Stradiņš University, Rīga Stradiņš University, Universitas Rigensis Stradina, Riga Medical Institute, Medical Academy of Latvia, RSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Latvia

Funder Name
Recovery and Resilience Plans - European Commission

Funder Name
Latvijas Republika

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be stored in a non-publicly available repository (Riga Stradiņš University Institutional Repository Dataverse: https://dataverse.rsu.lv/dataverse/rsu).

• The type of data stored: .csv format table of raw data, codebook.
• The process for requesting access (if non-publicly available): The data will be available by contacting the authors via dataverse.rsu.lv
• Timing for availability: Data will be available after the publication of research results (approximately from 01.04.2028)
• Whether consent from participants was required and obtained: Yes, patient consent will be obtained. Patients signed a consent form.
• Comments on data anonymization: Data will be anonymized using Amnesia (https://amnesia.openaire.eu/)
• Any ethical or legal restrictions: The permission of the RSU Ethics Committee has been received for conducting the research and publishing the data.
• Any additional comments: No

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes