

Prevalence of osteoporosis in Indian patients undergoing elective arthroplasty and spinal procedures

Submission date 14/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/08/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to assess the prevalence of osteoporosis and/or osteopenia in patients undergoing elective arthroplasty and spinal procedures in India. Osteoporosis is a health condition that weakens bones, making them fragile and more likely to break. The stage before osteoporosis is called osteopenia, when bone density is less than normal. Arthroplasty is a surgical procedure to restore the function of a joint.

Who can participate?

Men aged 60 years and over and women aged 55 years and over undergoing arthroplasty or spinal procedures.

What does the study involve?

Patients undergo a bone scan to see if they are osteoporotic or osteopenic. Their fracture risk is assessed using an online questionnaire.

What are the possible benefits and risks of participating?

Checking for osteoporosis in patients undergoing elective arthroplasty and spinal procedures may decrease complications. There is no risk to patients as this is not an interventional study.

Where is the study run from?

Cadila Healthcare (India)

When is the study starting and how long is it expected to run for?

February 2019 to June 2020

Who is funding the study?

Cadila Healthcare (India)

Who is the main contact?
Dr Sujoy Kumar Bhattacharjee
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

ostivia/01

Study information

Scientific Title

A prospective multicenter study on the prevalence of osteoporosis in Indian patients undergoing elective arthroplasty and spinal procedures

Acronym

PROPESI

Study objectives

To determine the preoperative prevalence of osteoporosis and/or osteopenia in Indian patients undergoing prospective elective arthroplasty/spinal procedures and to evaluate overall bone quality in these patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/07/2019, Sangini Hospital Ethical Committee (Sangini Hospital, First Floor, Santorini Square, B/h Abhishree Complex, Opp. Star Bazar, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat, India; +91 (0)79 40056171; sanginihospitalec@gmail.com), ref: ECR /147/Inst/GJ/2013/RR-16

Study design

Prospective cross-sectional observational open-label multi-centric study

Primary study design

Observational

Secondary study design

Epidemiological study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please contact Dr Suyash Bharat (+91 (0)9760267848) for a hard copy

Health condition(s) or problem(s) studied

Osteoporosis

Interventions

This is a prospective, multicenter, cross-sectional study that will include males (≥ 60 years) females (≥ 55 years) undergoing arthroplasty or spinal procedures. Bone mineral density (BMD) at the femoral neck and lumbar spine will be measured by dual-energy X-ray absorptiometry (DEXA). The Fracture Risk Assessment Tool (FRAX®) will be used to evaluate fracture risk.

Intervention Type

Procedure/Surgery

Primary outcome measure

Bone mineral density measured using DEXA scan in patients undergoing orthopedic procedure at baseline

Secondary outcome measures

Fracture risk measure using FRAX score at baseline

Overall study start date

01/02/2019

Completion date

01/06/2020

Eligibility

Key inclusion criteria

1. Patients giving informed consent to participate in the study
2. Gender - either male or female
3. Age: male ≥ 60 years and female ≥ 55 years
4. Patients who are undergoing elective orthopedic and spinal surgical procedures

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

140

Total final enrolment

127

Key exclusion criteria

1. Not willing or not able to sign informed consent
2. Patients who underwent spine surgery in the last 2 years
3. Patients on concomitant chemotherapy drugs

Date of first enrolment

31/07/2019

Date of final enrolment

01/06/2020

Locations

Countries of recruitment

India

Study participating centre**Dr Dilip Shah Clinic**

1/7 Kennaway House 63 a Proctor Road

Opp Edubridge International School

Grant Road (e)

Mumbai

India

400004

Study participating centre**Dr Sandeep Garg Clinic**

c 397, Nirala Nagar

Near Saraswati Shishu Mandir

Lucknow

India

226020

Study participating centre**Medi Surge Hospital**

Mithakali Circle

Navranpura

Ahmedabad

India

380009

Study participating centre**Sarvodaya Hospital**

Sector 8, YMCA Road, Faridabad Haryana

Faridabad

India

121006

Study participating centre

Dr Vikas Mehra Clinic

1501, Sector 33d
Chandigarh
India
160022

Study participating centre

Mordern Ortho Clinic

Besides Kalinga Stadium
751, Behera Sahi Road
Unit 4, Nayapalli
Bhubaneswar
India
751012

Study participating centre

Vikram Hospital

Anne's College N.o. 71/1, Millers Road
Bengaluru
India
560052

Study participating centre

Dr S Arumugam Clinic

20, Gopathi Narayanaswami Chetty Road
Satyamurthy Nagar
T Nagar
Chennai
India
600017

Study participating centre

Dr Satish Gore Clinic

1128, Fergusson College Road Model Colony
Shivajinagar
Pune
India
411016

Study participating centre
Dr Vinod Agarwal
Soni House
401, CD Barfiwala Road
Andheri West
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400049

Sponsor information

Organisation
Cadila Healthcare (India)

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Sponsor type
Industry

Website
<http://www.zyduscadila.com/>

ROR
<https://ror.org/03ktyvw44>

Funder(s)

Funder type
Industry

Funder Name
Cadila Healthcare Ltd

Results and Publications

Publication and dissemination plan

The researchers intend to publish the epidemiological data.

Intention to publish date

21/07/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Suyash Bharat (suyash.bharat@zyduscadila.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		10/07/2019	08/07/2021	No	No
Results article		26/07/2022	02/08/2022	Yes	No