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

Submission date
14/06/2021

Recruitment status
No longer recruiting

Registration date
19/06/2021

Overall study status
Completed

Last Edited
02/08/2022

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
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

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Additional identifiers

Protocol serial number
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

Primary study design
Observational

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

Study type(s)
Diagnostic

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

Key secondary outcome(s)
Fracture risk measure using FRAX score at baseline

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
Mumbai
India
400049

Sponsor information

Organisation

Cadila Healthcare (India)

ROR
https://ror.org/03ktyvw44

Funder(s)

Funder type
Industry

Funder Name
Cadila Healthcare Ltd

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 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?
Results article		26/07/2022	02/08/2022	Yes	No
Protocol file		10/07/2019	08/07/2021	No	No