ISRCTN10328801 https://doi.org/10.1186/ISRCTN10328801

Evaluation of the TEKTONA® system designed to restore vertebral height in the treatment of vertebral fractures by compression

Submission date
13/04/2023

Recruitment status
No longer recruiting

Registration date
14/06/2023

Overall study status
Completed

Last Edited
02/06/2023

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
This is a post-market study to confirm the performance and safety of the TEKTONA system in the treatment of vertebral compression fractures. A compression fracture is usually defined as a vertebral bone in the spine that has decreased at least 15 to 20% in height due to fracture. The TEKTONA medical device reduces the vertebral fracture and allows the cement injection in the vertebra to consolidate it.

Who can participate?
Patients aged 18 years and over with vertebral compression fracture

What does the study involve?
The patient is screened during the preoperative visit. Those patients who are eligible for the study are invited to participate in the study. After reading the information letter, the patients should let their surgeon know if they agree/consent before any data collection. Clinical and radiographic data are collected at their preoperative, surgical, and postoperative clinical visits performed as the site standard of care.

What are the possible benefit and risks of participating?
As an observational study, there is no benefit or risk for the patients participating in the study.

Where is the study run from?
Spineart SA (Switzerland)

When is the study starting and how long is it expected to run for?
January 2016 to December 2020

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

Contact name
Mrs Dervilla Bermingham

Contact details
3, chemin du Pré Fleuri
Plan-les-Ouates
Switzerland
1228
+41 (0)225701261
dbermingham@spineart.com

Additional identifiers

Protocol serial number
P61_CLD001

Study information

Scientific Title
Evaluation of the safety and performance of the compression spinal fracture treatment system, TEKTONA® prospective study

Acronym
TEKTONA® system

Study objectives
The TEKTONA® system is designed to restore the vertebral height and reduce the angle of vertebral kyphosis, for the treatment of osteoporotic or osteopathic vertebral settlement fractures (FTV) Type A1 and A2 (a gap between fragments of less than 2 mm) and A3 in the MAGERL classification.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2016, CPP Ile-de-France VI (Groupe Hospitalier Pitié-Salpêtrière, 47 Boulevard de l'Hôpital, 75013, Paris, France; +33 (0)1 42 16 16 83; cppidf6.salpetriere@yahoo.fr), ref: ID RCB 2016-A00150-51, CCTIRS # 16-640

Primary study design

Observational

Study design
Post-market clinical follow-up (PMCF) prospective multicenter single-arm observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vertebral compression fracture, stable type, without neurological deficit

Interventions
Evaluation of qualitative and quantitative of pre-, peri- and post-operative data. Comparison between pre-and post-operative values provided by radiological parameters, pain medication, VAS, ODI and SF-12 scores. The risk assessment is determined by the rate of complications observed.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
TEKTONA®

Primary outcome(s)
1. Risks are measured by the incidence of perioperative complications and safety reporting and post-operative risks (adverse events reporting, radiological assessments at 6, 12 and 24 months)
2. Restoration of vertebral height (mm) and reduction of kyphosis (Cobb Angle) at the level operated is measured by comparing radiological images pre-surgery, perioperative, immediate post-surgery, at 6-, 12- and 24-months post-surgery

Key secondary outcome(s)
1. Volume of cement injected and cement distribution (vertebral and horizontal) is measured (in ml) at surgery
2. Effectiveness of the system is measured by the duration of post-operative hospitalization
3. Pain is evaluated by changes in the use of pain medication and the visual analogue score (VAS) score pre-surgery, immediate post-surgery, at 6-, 12- and 24-months post-surgery
4. Quality of life is measured using the SF-12 questionnaire preoperatively, immediate postoperatively and at 6, 12 and 24 months and time between intervention and back to work
5. Functional evaluation using Oswestry Disability Index (ODI) score preoperatively, immediate postoperatively and at 6, 12 and 24 months

Completion date
07/12/2020

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Presenting one or more three stable vertebral fractures at non-adjacent levels, fractures type A1.1, A1.2, A1.3, A2 (gap between fragments less than 2 mm) and A3.1, A3.2, A3.3 according to Magerl classification
3. Presenting vertebral traumatic fracture(s), due to high-energy trauma, or osteoporotic fall of one's own height
4. Able to understand the investigation protocol, agree with the investigation plan, and complete the necessary documents
5. Who voluntarily signed the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Anterior treatment with cyphoplasty at the fractured level
2. Unstable fractures of type B or C according to Magerl
3. Size of the pedicules incompatible with safe access to the instrument

Date of first enrolment
22/11/2016

Date of final enrolment
12/12/2018

Locations

Countries of recruitment
France

Study participating centre
Hopital La Pitié-Salpêtrière
Service de Chirurgie Orthopédique et Traumatologie
47-83 Bd de l'Hôpital
Paris

France
75651

Study participating centre
Hôpital Michallon
Service de Chirurgie Orthopédique et Traumatologie
Grenoble
France
38043

Study participating centre
Hôpitaux Universitaires de Strasbourg
Service de Chirurgie du Rachis
1, Place de L'Hôpital
Strasbourg
France
67000

Sponsor information

Organisation
Spineart (Switzerland)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com.
The type of data that will be shared: clinical data of the study
Dates of availability: up to 2035
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: All subjects' data are pseudo-anonymized
Any ethical or legal restrictions: No restrictions

IPD sharing plan summary

Available on request