ISRCTN21241251 https://doi.org/10.1186/ISRCTN21241251

A study of the effectiveness of hip replacement with TNS alloy stems in patients with hip joint dysfunction

Submission date
23/10/2021

Recruitment status
No longer recruiting

Registration date
26/10/2021

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A hip replacement is a common type of surgery where a damaged hip joint is replaced with an artificial one (prosthesis). The aim of this study is to investigate whether TiNbSn (TNS) alloy stems hip prostheses can prevent loosening, stress shielding, and thigh pain after hip replacement.

Who can participate?
Patients who are 20 years of age or older, have not had previous hip surgery, and are eligible for surgical treatment due to severe hip joint damage caused by osteoarthritis.

What does the study involve?
Participants undergo total hip replacement surgery using TNS stems. X-rays are taken immediately after the surgery and after 3 weeks, 6 weeks, 3 months, 6 months and 1 year.

What are the possible benefits and risks of participating?
The advantages are that the metal is free from toxic toxins such as vanadium and may prevent bone atrophy (reduction in bone density) and thigh pain after surgery. The disadvantage is that the material has not yet been used for human prostheses, so there are some unknowns. There is a possibility of infection and other problems similar to normal hip joint surgery.

Where is the study run from?
Tohoku University Hospital (Japan)

When is the study starting and how long is it expected to run for?
March 2016 to September 2018

Who is funding the study?
Mizuhos Corporation (Japan)

Who is the main contact?
Dr Yu Mori
yu-mori@med.tohoku.ac.jp

Contact information

Type(s)
Public

Contact name
Dr Yu Mori

ORCID ID
https://orcid.org/0000-0002-8225-4690

Contact details
1-1 Seiryo-machi
Sendai
Japan
9808574
+81 (0)22 717 7245
yu-mori@med.tohoku.ac.jp

Additional identifiers

Protocol serial number
201506-1

Study information

Scientific Title
A multicenter, open-label study of total hip arthroplasty with TNS alloy stems in patients with hip dysfunction

Acronym
TNSTHA

Study objectives
A TiNbSn (TNS) alloy stem with the functional gradient properties of Young’s modulus and strength could prevent the stress-shielding problem and improve the postoperative outcome of cementless total hip arthroplasty (THA).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 08/03/2016, the research ethics board approval of Tohoku University Hospital (1-1 Seiryo-machi, Sendai, Miyagi, Japan; +81 (0)22 728 4105; ec@rinri.hosp.tohoku.ac.jp), ref: #201506-1

Study design
Multicenter single-arm open-label interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip joint disorder requiring total hip replacement surgery

Interventions
Total hip arthroplasties using the TNS alloy stem are performed in cases that meet the inclusion criteria. Radiographs are taken immediately after the surgery, at 3 weeks, 6 weeks, 3 months, 6 months, 1 year postoperatively.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
TNS alloy stem

Primary outcome(s)
1. Clinical outcomes assessed using the Japanese Orthopaedic Association (JOA) hip scores before the surgery, 6 weeks, 3 months, 6 months, and 1 year postoperatively
2. Pain, activities of daily life and mental health status assessed using the Japanese Orthopaedic Association Hip Disease Evaluation Questionnaire (JHEQ) before the surgery, 3 months, 6 months, and 1 year postoperatively

Key secondary outcome(s))
The inhibition of stress shielding by the TNS stem assessed using radiographic images at 12 months

Completion date
30/09/2018

Eligibility

Key inclusion criteria

1. Patients over 20 years of age
2. Preoperative diagnosis of osteoarthritis, avascular necrosis, or rheumatoid arthritis
3. Consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Previous operation (total hip arthroplasty, osteotomy, tenotomy around hip joint)
2. Bilateral hip disorder
3. Rheumatoid arthritis of Charnley category C (multiple joint disease or other disease limiting mobility)
4. Past history of deep venous thrombosis or pulmonary embolism, metal allergy, severe obesity (Body Mass Index >35.0 kg/m^2)
5. Severe diabetes mellitus
6. Infection around the hip joint

Date of first enrolment
01/04/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Japan

Study participating centre
Tohoku University Hospital
1-1 Seiryo-machi
Sendai
Japan
9808574

Study participating centre
Sendai Red Cross Hospital
2-43-3 Yagiyamahoncho
Sendai
Japan
9828501

Study participating centre
Osaki Citizen Hospital
3-8-1 Furukawahonami
Osaki
Japan
9896183

Sponsor information

Organisation
Mizuho (Japan)

ROR
https://ror.org/05e34ra63

Funder(s)

Funder type
Industry

Funder Name
Mizuho

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Anonymization procedures are used to ensure that individuals are not identified. Consent has been obtained from participants for publication and secondary use. As a rule, the researchers do not plan to release the data until the product is commercially available and the resulting paper is published.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/11/2021	29/11/2021	Yes	No
Results article		03/07/2023	04/07/2023	Yes	No