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Comparing the results of using strut bone graft from the iliac bone and cancellous bone graft from the iliac bone on large bone defects in the lower body

Submission date
13/02/2023

Recruitment status
No longer recruiting

Registration date
15/03/2023

Overall study status
Completed

Last Edited
28/02/2023

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 study is looking at a new way to fix large bone defects in the lower body using bone graft from the iliac bone. In the past, using simple bone grafting has not been successful for fixing large bone defects. This study will compare using a strut-type bone graft from the iliac bone to using a cancellous bone graft from the iliac bone. The goal is to see if the strut-type bone graft is a good solution with fewer complications.

Who can participate?
Patients over 18 years of age with bone defects in the long bones of the lower extremity, treated by autogenous iliac bone graft (AIBG)

What does the study invlove?
Analyzing the outcomes of autogenous strut bone graft in large bone defects of ≥ 5 cm in the lower extremities and to compare it with the autogenous cancellous bone graft, which is accepted as the golden standard of treatment in bone defects of < 5 cm.

What are the possible benefits and risks of participating?
You can receive specialized treatment for bone defects in the lower limbs. Complications may occur during treatment, including infection, bleeding, pain, and damage to nerves and blood vessels.

Where is the study run from?
Hanyang University Seoul Hospital, 222-1 Wangsimni-ro, Seongdong-gu, Seoul 04763 KOREA

When is the study starting and how long is it expected to run for?
This study is a retrospective study, and all data collection and analysis were completed in December 2021, starting with the study design plan in December 2019.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Kyu Tae Hwang, M.D, Ph.D.
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Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2021-05-039

Study information

Scientific Title
The impact of autogenous iliac strut bone graft on large bone defect of lower extremity compared with autogenous iliac cancellous bone graft: a retrospective cohort study

Acronym
Strut AIBG

Study objectives
Autogenous bone graft in strut form might show favorable union rate in large bone defects of ≥ 5 cm with minimal complications

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2021, Hanyang University Hospital Instituional review board (222-1 Wangsimni-ro, Seongdong-gu, Seoul, 04763, South KOREA; +82 (2)2290 9651; icshin@hanyang.ac), ref: HYUH 2021-05-039

Study design
Single center interventional non-randomized retrospective cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Performing autogenous strut bone graft in patients with large bone defects of ≥ 5 cm in the lower extremities.

Interventions
Based on the types of the grafted bone, the patients were classified into two groups: strut bone graft group and cancellous bone graft group. All bone grafts were harvested along the anterior iliac crest through the anterior approach. The strut-type corticocancellous bone graft was harvested using an osteotome, and a cortical window was used for harvesting the cancellous bone graft. Strut bone graft was performed only when the bone defect length was ≥ 5 cm. All of the bone graft procedures were performed by a single orthopedic trauma surgeon.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Union and time to union were evaluated using a Radiographic Union Scale of Tibial Fractures (RUST) at 1, 2, 3, 6, 9, and 12 months postoperatively.

Key secondary outcome(s))
1. Complications measured retrospective medical record review over admission and outpatient follow-up period
2. Reoperations measured using retrospective medical record review over admission and outpatient follow-up period

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. Bone defects in the long bones of the lower extremity
2. Bone defects treated by autogenous iliac bone graft
3. Age over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Age younger than 18 years
2. Bone defects caused by pathologic fracture or tumor resection
3. Less than 12 months of follow-up period

Date of first enrolment
23/03/2011

Date of final enrolment
02/04/2020

Locations

Countries of recruitment
Korea, South

Study participating centre
Hanyang University Soeul Hospital
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Sponsor information

Organisation
Hanyang University Seoul Hospital

ROR
https://ror.org/04n76mm80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Kyu Tae Hwang, M.D., Ph.D, e-mail: md0713@hanmail.net

IPD sharing plan summary
Available on request