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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?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet
Not applicable (retrospective study)

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/12/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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
222-1 Wangsimni-ro
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Sponsor information

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Sponsor type

Hospital/treatment centre

Website
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ROR
https://ror.org/04n76mm80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal

Intention to publish date
30/04/2023

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