

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	<input type="checkbox"/> Prospectively registered
Registration date 15/03/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/02/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 involve?

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

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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 Institutional 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 Seoul Hospital

222-1 Wangsimni-ro

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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