

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Design, development and clinical evaluation of a new prosthetic suspension system for lower limb amputees

Protocol summary

Summary

Amputation is a complex problem for patients, the health care system, and the country. Dysvascular disease associated with diabetes accounts for about 82% of all limb losses. More than 180 million patients suffer from diabetes according to data from the WHO, of which Malaysia alone will face 2.48 million in 2030 that is 164% increase compared to year 2000. Safe and effective use of prosthetic limbs requires that the prosthesis be suspended consistently and comfortably on the limb during patient activity. Selection of the optimal suspension is paramount to achieving efficient and safe prosthetic ambulation. An improperly fitting suspension may result in discomfort, pistoning of the device around the residual limb, skin breakdown, increased energy consumption, gait deviations, and falls. A good suspension reduces the risk of skin breakdown or irritation by minimizing the limb movement (pistoning) inside the prosthesis. The research should develop a new prosthetic suspension system to address some of the shortcomings of current designs. Many choices in suspension system are available, and clinicians often rely on personal intuition and experience to choose which system is appropriate for which patient. Clinicians, administrators, medical researchers, and third-party payers are required to make decisions about the quality of care and the effectiveness of the prosthesis. The use of silicone liners in prosthetics is not new. It has two main functions, namely, protection of the amputation stump and suspension of the prosthesis. Suspension in silicone suction socket can be achieved in different ways, such as shuttle lock, sleeve, or a Hypobaric Sealing Membrane (HSM) around the liner (a new technology in silicone liners). On the basis of the researcher's experience, available suspension systems for lower limb amputations have not yet fully addressed the patients' needs. A great number of amputees have some problems in their stump, like contracture, diabetic, or skin problem and they complain about the suspension system in terms

of donning and doffing, gait and pain. It was the starting point to deal with this topic in general and invent a new suspension system which can cover some of the shortcomings of the existing suspension systems for lower limb amputees. This study aims to: □ To design and fabricate a new prosthetic suspension system. □ To obtain kinematics and kinetics of trans-tibial and trans-femoral amputees gait using the new suspension system and compare that to the locking liner and Seal-in liner by using motion analysis approach. □ To evaluate the biomechanical characteristics of each of the suspension systems (new system, locking or seal-in) in terms of comfort, function and satisfaction in amputees with normal stump, skin problems, flexion contracture, and diabetic or vascular diseases.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061813706N1**

Registration date: **2013-07-02, 1392/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-02, 1392/04/11

Registrant information

Name

Arezoo Eshraghi

Name of organization / entity

University of Malaya

Country

Malaysia

Phone

0060379676808

Email address

arezoo@um.edu.my

Recruitment status**Recruitment complete****Funding source**

UM/MOHE/HIR grant (project no: D000014-16001)

Expected recruitment start date

2012-03-21, 1391/01/02

Expected recruitment end date

2013-03-31, 1392/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, development and clinical evaluation of a new prosthetic suspension system for lower limb amputees

Public title

Prosthetic suspension system

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria would be: - lower limb amputee - age 20 to 80 - no medical contraindications for engaging in physical activities - no ulcer or open wound in the limb - old prosthetic user (more than 1 month) - no upper limb weakness or disability

Exclusion criteria: - ulcer or open wound in the limb - Serious health condition (heart attack, dialysis, ...)

AgeFrom **20 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **15****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Ethics Committee, University Malaya Medical Center

Street address

Lembah Pantai

City

Kuala Lumpur

Postal code

59100

Approval date

2012-03-21, 1391/01/02

Ethics committee reference number

907.26

Health conditions studied**1****Description of health condition studied**

Lower limb amputation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Ambulation

Timepoint

4 weeks after use

Method of measurement

kinematic & kinetic gait analysis

Secondary outcomes**1****Description**

Interface pressure

Timepoint

4 weeks after use

Method of measurement

Pressure mapping

Intervention groups**1****Description**

New prosthetic suspension system, Pin/lock system, Seal-In system

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

University Malaya Medical Centre

Full name of responsible person

Street address

City

Kuala Lumpur

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

UM/MOHE/HIR grant (project no: D000014-16001)

Full name of responsible person

Assoc. Prof. Dr. Noor Azuan Abu Osman

Street address

Deputy Dean office, Faculty of Engineering

City

Kuala Lumpur

Grant name

Grant code / Reference number

D000014-16001

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

UM/MOHE/HIR grant (project no: D000014-16001)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Malaya

Full name of responsible person

Noor Azuan Abu Osman

Position

Deputy Dean/PhD

Other areas of specialty/work

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Arezoo Eshraghi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty