Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 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

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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, ...)
Age
From **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
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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
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Noor Azuan Abu Osman
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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