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The effect of oral channa striatus extract on post lower segment caesarian section (LSCS) women

Submission date
24/12/2014

Recruitment status
No longer recruiting

Registration date
21/01/2015

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Channa striatus (Haruan) is a fresh water fish that has been eaten for decades by women that have just given birth to aid wound healing after a caesarian. There have been extensive studies done on the biomedical properties of this extract (that is, how it works in the body) but there has not been, to date, any clinical trials to test if it really does help wounds to heal. The aim of this study is to get scientific evidences to substantiate the claims.

Who can participate?
Healthy women aged 18-40 who have just had their first baby by caesarian section.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given 500mg of channa striatus extract a day for six weeks after their caesarian section. Those in group 2 are given 500mg maltodextrin (a placebo, or dummy pill) a day for six weeks after their caesarian section. Each participant then takes part in a number of assessments to measure, amongst other things, the amount of pain they are feeling, how well their wound is healing and how satisfied they are with the treatment 3 days after their operation and then after two weeks, four weeks and six weeks.

What are the possible benefits and risks of participating?
All study procedures are free to participants and they benefit from information about their medical condition. There are no possible risks to taking part in the study.

Where is the study run from?
Hospital University of Science, Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?
March 2011 to March 2014

Who is funding the study?
University of Science, Malaysia (Malaysia)

Who is the main contact?
Professor Azidah Abdul Kadir

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effect of oral channa striatus extract on post lower segment caesarian section (LSCS) women: a randomized, double-blind, placebo-controlled study

Study objectives
1. There is significant reduction of post-operative pain in the Channa striatus group compared to placebo group
2. There is significant improvement of wound healing based on WES, VAS and patient's satisfaction score in the Channa striatus group compared to placebo group
3. There is no significant difference in safety profile between Channa striatus group and placebo group
4. There is significant difference in the uterine involution and blood supply to the uterus in terms ultrasound measured between Channa striatus group and placebo group
5. There is significant difference in the wound healing measured by mean resistive index (RI) and pulsatility index (PI) and of the artery of the superficial skin wound between channa striatus group and placebo group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Research Committee (Human) of Universiti Sains Malaysia (with the permission of Director of Hospital Universiti Sains Malaysia), 31/12/2009, ref: USMKK/PPP/JEPeM [220.3.(04)]

Study design
Randomized double-blind placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
To assess the effect of oral channa striatus extract on post lower segment caesarian women in terms of post operative pain, wound healing, safety profile and uterine involution.

Interventions
The patients were randomized to two groups in the ratio of 1:1 using computer develop generation numbers in the block of four. The treatment group was prescribed 500 mg (2 capsules) per day of freeze dried channa striatus extract while the placebo group was given 500 mg (2 capsules) per day of maltodextrin. Both arms took the medication for 6 weeks.

Intervention Type
Supplement

Primary outcome(s)
1. Post-operative pain score
2. Wound healing based on:
2.1. Wound Evaluation Scale (WES)
2.2. Visual Analogue Scale (VAS)
2.3. Patient’s satisfaction score (PSS)
3. Safety profile based on Renal Function Test (RFT), Liver Function Test (LFT) and Full Blood Count (FBC)
4. Mean anteroposterior measurement of the uterus in longitudinal and oblique transverse planes
5. Mean resistive index (RI) and pulsatility index (PI) of the uterine artery
6. Mean resistive index (RI) and pulsatility index (PI) and of the artery of the superficial skin wound

Measured at baseline (day 3), two weeks, four weeks and six weeks post-operatively.

Key secondary outcome(s))
N/A

Completion date
14/03/2014

Eligibility

Key inclusion criteria
1. Age between 18 and 40 years
2. No present active medical, surgical and gynecological problems
3. First LSCS (elective or emergency)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
66

Key exclusion criteria
1. Taking any form of herbal extract in the last 3 months before study entry and during the study period
2. History of drug or alcohol abuse.
3. Taking fresh channa striatus during study period
4. Patient taking warfarin or heparin
5. Clinical relevant cardiovascular, gastrointestinal, hepatic, neurologic, endocrine, haematologic, connective tissue disease or other major systemic diseases that would influence the interpretation of results
6. Patients with medical disorder requiring steroid or immunosuppressive therapy
7. Patient with chronic cough or other condition which may cause a rise in intra-abdominal pressure
8. Presence of any congenital anterior abdominal wall defects
9. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study.
10. Evidence of uncooperative attitude, including poor compliance including inability to attend follow-up visit

Date of first enrolment
15/03/2011

Date of final enrolment
31/01/2013

Locations

Countries of recruitment

Malaysia

Study participating centre
Hospital University of Science, Malaysia
Kubang Kerian
Malaysia
15200

Sponsor information

Organisation
University of Science, Malaysia

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
University/education

Funder Name
University of Science, Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/07/2015		Yes	No
Dataset			09/02/2023	No	No
Protocol (other)			09/02/2023	No	No