

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

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| <b>Submission date</b><br>24/12/2014   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>21/01/2015 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>09/02/2023       | <b>Condition category</b><br>Pregnancy and Childbirth | <input checked="" type="checkbox"/> 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**  
Dr Azidah Abdul Kadir

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 developed 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 measure**

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.

### **Secondary outcome measures**

N/A

### **Overall study start date**

15/03/2011

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

### **Target number of participants**

84

### **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

**Sponsor details**

Department of Family Medicine

School of Medical Sciences

Health Campus

Kubang Kerian

Malaysia

16150

**Sponsor type**

University/education

**ROR**

<https://ror.org/02rgb2k63>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Science, Malaysia

# Results and Publications

## Publication and dissemination plan

### Intention to publish date

### 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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results | 29/07/2015   |            | Yes            | No              |
| <a href="#">Dataset</a>          |         |              | 09/02/2023 | No             | No              |
| <a href="#">Protocol (other)</a> |         |              | 09/02/2023 | No             | No              |