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Macrogol versus lactulose in the treatment of constipation in pregnancy

Submission date	Recruitment status	[X] Prospectively registered
13/08/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2024	Digestive System	

Plain English summary of protocol

Background and study aims
Chronic constipation is common, affecting up to 60.7% of pregnant women. It has a remarkable impact on quality of life in various aspects including discomfort, poor general health, and physical, psychological and social functions. To date, evidence is scarce with regards to the treatment of this disorder in pregnancy. Polyethylene glycol has been shown to be in favour as the first line of treatment of chronic constipation in the general population. This study aims to evaluate the effectiveness and tolerability of this drug in women with chronic constipation during their pregnancy.

Who can participate?
Women in their third trimester of pregnancy with chronic constipation

What does the study involve?
The study involves comparing polyethylene glycol (macrogol) and lactulose. Participants will be randomly allocated to receive one of the two treatments for up to 4 weeks. Participants answer a few questionnaires before starting the treatment and at the end of the treatment. Over the course of treatment, participants complete a bowel diary.

What are the possible benefits and risks of participating?
Possible benefits come from the treatment that will be given free of charge and at the same time will treat their symptoms according to the standard treatment of constipation. The possible adverse events that can occur include abdominal bloating, vomiting, flatulence and diarrhoea. At the moment, there are no reported severe adverse events with these two treatments.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
February 2020 to October 2022

Who is funding the study?
University Malaya Medical Centre (Malaysia)

Who is the main contact?
Azyyati binti Hassan
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
NMRR-20-1500-55812

Study information

Scientific Title
Randomized controlled trial: low dose polyethylene glycol (macrogol 4000) versus lactulose in the treatment of constipation in pregnancy

Study objectives
Low dose polyethylene glycol (PEG) is more effective in the treatment of chronic constipation in pregnancy compared to lactulose.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/8/2020, Medical Research Ethics Committee, University Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +6 (0)3 7949 3209/2251; ummc@ummc.edu.my), ref: 202071-8852

Study design
Single-center Interventional open-labelled randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Constipation in pregnancy

Interventions
Participants will be randomized via block randomization into either a group taking macrogol or a control group taking lactulose. Macrogol 4000 is given as one sachet a day (10 g) and can be adjusted up to two sachets a day. Lactulose is given as 15 ml a day (10 g) and can be adjusted up to 30 ml/day. Both are osmotic laxatives, taken in oral form. The duration of treatment is up to 4 weeks. Participants answer questionnaires before starting the treatment and at the end of the treatment. Over the course of treatment, participants will be given a bowel diary.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Macrogol 4000 (Forlax), Lactulose (duphalac)

Primary outcome(s)
1. Number of women responding in terms of Complete Spontaneous Bowel Movements (CSBMs), defined as three or more Complete Spontaneous Bowel Movements (CSBMs) per week for at least 3 out of 4 weeks of total treatment, measured at baseline and week 4 of treatment
2. Number of women responding in terms of improvement in symptoms measured by PAC-SYM 12 items, where a response is defined by a decrease in score of ≥1 from the baseline, measured at baseline and week 4 of treatment

Key secondary outcome(s))
1. Tolerability in term of side effects over the course of treatment weeks:
1.1. Side effects including vomiting, abdominal bloating, flatulence and diarrhoea, reported in bowel diary over the course of 4 weeks treatment and measured at week 4
1.2. Diarrhoea defined by bowel movements more than three times a day with stool consistency measured using Bristol Score Chart score 6-7 reported in the bowel diary over the whole 4 weeks treatment and measured at week 4
2. Typical stool consistency measured using Bristol stool chart at baseline and at week 4 of treatment
3. The use of rescue treatment reported in the bowel diary over the course of 4 weeks treatment and measured at week 4 of treatment
4. Discontinuation of treatment due to adverse effects reported in the bowel diary over the course of 4 weeks treatment, measured at week 4 of treatment
5. First bowel movement after the first administration reported in the bowel diary and measured

at week 4 of treatment
6. Patient improvement of specific constipation symptoms following the three subscales in PAC-SYM 12-items at baseline and week 4 of treatment
7. Patient improvement in quality of life including satisfaction as measured by PAC-QOL 28-items at baseline and week 4 of treatment

Completion date
15/10/2022

Eligibility

Key inclusion criteria
1. Pregnancy in the third trimester from 28-32 weeks (32 weeks defined by up to 32 weeks + 6 days)
2. Fulfil ROME IV criteria for chronic constipation
3. Consented for inclusion in the study
4. Have telephone access and agree to telephone interview

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
360

Key exclusion criteria
1. Pre-existing gastrointestinal disease or surgery
2. Pre-existing medical diseases that can alter gastrointestinal functions (hypothyroidism, diabetes mellitus) and those suffering from severe liver, renal or cardiac diseases
3. Hypersensitivity to lactulose or polyethylene glycol
4. Persistent nausea or vomiting in pregnancy
5. Unable to give consent

Date of first enrolment
25/08/2020

Date of final enrolment
08/09/2022

Locations

Countries of recruitment

Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will available upon request from the principal investigator (Azyyati Hassan; atieasan@gmail.com) after the overall trial end date. Datasets are confidential and any data sharing will have to go through the Medical Research Ethics Committees at University Malaya Medical Centre.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/02/2024	15/04/2024	Yes	No