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Comparison between Gaviscon and omeprazole for gastroesophageal reflux in pregnancy

Submission date	**Recruitment status**	[X] Prospectively registered
16/10/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/10/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/02/2021	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gastroesophageal reflux disease (GERD) is defined as complications resulting from the backflow of stomach contents into the mouth. The occurrence of GERD in the general population in Malaysia is 9.3%. However, in pregnancy the occurrence is higher at about 30-80% and increases throughout the pregnancy. Diagnosis of this condition can be made with a Gastroesophageal Reflux Disease Questionnaire (GerdQ), where scores of 8 and over are defined as having GERD. A survey of 142 pregnant women at the antenatal clinic of University Malaya Medical Centre shows that 45 women (31.7%) have GERD. Out of this, 31 women (21.8%) are keen to seek treatment for GERD. Reflux suppressants such as Gaviscon form a raft in the stomach and are able to reflux in place of the stomach contents. They are retained in the stomach for up to 4 hours. A previous study found that Gaviscon is safe for use in pregnancy. Omeprazole is a drug that is used to reduce the acid production of the stomach for up to 36 hours. Previous studies showed that Omeprazole does not increase the risk of birth defects. GERD in pregnancy is commonly treated with omeprazole and Gaviscon, but there has not been a direct comparison made between these two treatments. Hence the aim of this study is to compare the effectiveness of Gaviscon and omeprazole in treating GERD in pregnancy.

Who can participate?
Pregnant women aged 18-40 with GERD from 14 weeks until 38weeks of gestation

What does the study involve?
Participants are allocated into two treatment groups: Gaviscon syrup three times a day or an omeprazole tablet once a day. Both treatments are given for 14 days. Participants are required to answer two questionnaires before starting the treatment, after 7 days and after 14 days of starting the treatment. Participants are also required to complete a symptom diary daily for 14 days after starting the treatment. This diary is then submitted to the investigator at the end of the study.

What are the possible benefits and risks of participating?
The treatment given in this study may help to resolve or reduce the symptoms of GERD. It is not expected to cause any major harm to the participants.

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?
August 2020 to December 2021

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

Who is the main contact?
Dr Tuscianthi Deva Tata
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2020713-8883

Study information

Scientific Title
A comparative study of Gaviscon and omeprazole for gastroesophageal reflux in pregnancy: a prospective randomized controlled trial

Study objectives

Omeprazole and Gaviscon are equally effective at reducing the symptom frequency and severity of GERD in pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2020, Medical Research Ethics Committee of University of Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3 79493209; iresearch@ummc.edu.my), ref: NMRR ID NO: 2020713-883

Study design
Prospective open-label randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Gastroesophageal reflux disease in pregnancy

Interventions
1. Pregnant women attending antenatal clinic UMMC are screened for inclusion and exclusion criteria.
2. Eligible participants are then diagnosed with GERD using GERD questionnaire in dual language. The questionnaire is distributed in the antenatal clinic and collected immediately once completed. Participants with score ≥ 8 from GerdQ are eligible for this study.
3. Participants who agree to be enrolled into the study are asked to sign consent forms prior to enrolment into this study.
4. Participants will be interviewed by the investigator to obtain participant's characteristics and Case Report Form is filled up by the investigator at baseline.
5. Participants are interviewed for further baseline information based on GERD-HRQL questionnaire.
6. Randomization of the treatment is performed by the staff nurse in charge with the opening of a random sealed and opaque envelope. The envelopes are kept at an allocated place in the antenatal clinic. Any opened/unsealed envelopes are discarded. Participants are randomly allocated at a 1:1 ratio to two treatment groups:
6.1. Gaviscon syrup 10 ml, three times a day, taken 30 min after meals
6.2. Omeprazole, 20 mg, once a day, taken 30 min prior to the first meal of the day
7. The study is an open-label study as the two treatments differ in appearance and taste, thus

the study is not conducted double-blind.
8. Participants are then advised to consume the treatment received for 14 days according to the proposed dosage and timing of consumption.
9. Participants with worsening of symptoms or hypersensitivity reaction towards the treatment received are then asked to present to hospital for reassessment and possibly change of medication.
10. GERD treatment response is assessed using the GerdQ, GERD-HRQL questionnaire and patient symptom diary.
11. Participants are required to answer GerdQ and GERD-HRQL questionnaire before starting the treatment, after 7 days and after 14 days of starting the treatment. Questionnaires were distributed via Google form. This method is found to be convenient for participants to respond promptly during the course of the study without having to be physically present at the hospital.
12. Participants are also required to fill a patient symptom diary daily for 14 days after initiating the treatment. This diary is then submitted to the investigator at the end of the trial.
13. No other treatment is given for the management of GERD, however, if symptoms worsen or patient develops any signs of hypersensitivity towards the treatment, participants are encouraged to report back to the care providers. Care providers have full discretion in deciding care in participant's best interest at all times if rescue treatment is needed or the adverse side effects are intolerable and whether the treatment needs to be discontinued.
14. Participants will be followed up every week via telephone interview to ensure compliance.
15. All the information collected are tabulated and analysed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gaviscon, omeprazole

Primary outcome measure
Relief of GERD measured using GerdQ on day 7 and day 14. Sufficient relief is defined as score ≤ 1 for question no 1, 2, 5 and 6. Complete relief is defined as a score of 0.

Secondary outcome measures
1. The severity of GERD symptoms and quality of life measured using Gerd-Health related Quality of Life (GERD-HRQL) upon recruitment on day 1 and after starting the treatment on day 7 and day 14
2. The time onset of the first 24-hour GERD symptom-free period after initial dosing as reported in patient symptom diary from day 1 to day 14
3. Use of any rescue treatment reported in the patient symptom diary over the course of 2 weeks

Overall study start date
01/08/2020

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Pregnant women aged 18 - 40 years
2. Gestational age 14 weeks to less than 38 weeks
3. Able to provide signed and dated informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
140

Key exclusion criteria
1. Pregnant women younger than 18 years or older than 40 years
2. Gestational age less than 14 weeks and more than 38 weeks
3. Presence of alarm symptoms (dysphagia, odynophagia, aspiration pneumonia, dysphonia, recurrent or persistent cough, gastrointestinal bleeding, frequent nausea/vomiting, persistent pain, iron deficiency anemia, and weight loss)
4. Presence of underlying gastrointestinal disease pre-pregnancy
5. Hypersensitivity to Gaviscon or omeprazole or both
6. Participants who are already on Gaviscon or omeprazole or both
7. Unable to provide signed and dated informed consent

Date of first enrolment
19/10/2020

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
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59100

Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
University Malaya Medical Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Tuscianthi Deva Tata (tuscianthi87@siswa.um.edu.my). The patient's identity will be kept confidential by using the initials of the names, this is explained in the informed consent that the patient will be asked to sign prior enrolling to this study. No information concerning the study or the data will be released to any unauthorized third party without prior written approval, in accordance with applicable laws and/or regulations. Only the

investigator has access to the data collected in this study and will be kept in safe locked place. This is quantitative data. The document will be retained for 7 years until August 2027, after the period of archiving, all study data will be destroyed by shredding.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			06/11/2020	No	No