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Management of metformin-induced gastrointestinal problems

Submission date	Recruitment status	[_] Prospectively registered
22/06/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/07/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2022	Other	

Plain English summary of protocol

Background and study aims
Metformin is a medicine used to treat type 2 diabetes that causes gastrointestinal (digestive) problems. The aim of this study is to find out whether the adverse effects of metformin can be treated with proton pump inhibitor drugs such as omeprazole and pantoprazole.

Who can participate?
Patients aged 26-85 with type 2 diabetes who are using metformin

What does the study involve?
This study consists of two phases. In the first phase patients with type 2 diabetes using metformin of different doses (500 mg, 850 mg and 100 mg) are randomly selected. Patients with symptoms of gastrointestinal problems are noted, along with dose, age, gender, frequency and way of taking metformin, all collected from the patient and their records. In the second phase of the study patients with gastrointestinal problems are divided into three groups. The first group receive omeprazole 40 mg, the second group receive pantoperazole 40 mg, and the third group receive non-drug treatment (i.e., take metformin during meal) for one month. Gastrointestinal symptoms are recorded before and after the treatment by interviewing the participants. Their blood sugar levels are also noted.

What are the possible benefits and risks of participating?
The benefit to patients is that their tolerance to metformin could be increased and their quality of life could be better. There are no possible risks to the patients.

Where is the study run from?
1. Allied Hospital
2. Faisalabad Diabetic Center
3. Diabetic Institute Pakistan

When is the study starting and how long is it expected to run for?
May 2017 to December 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Miss Madeeha Fatima
2. Miss Saleha Sadeeqa

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
49165218

Study information

Scientific Title

Management of metformin-induced gastrointestinal problems by pharmacological and non-pharmacological treatment

Study objectives
Metformin is a biguanide that causes gastrointestinal problems. To manage the adverse effects of metformin proton pump inhibitors were used to investigate the outcome on the adverse effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Board of Studies (BOS) and Advance Study Research Board (ASRB), Lahore College for Women University (LCWU), 26/05/2017
2. Hospital ethics committee Punjab Medical College Faisalabad, 19/07/2017, ref: PMC/PHRC /ERC/2017/11

Study design
The study consisted of two parts: in the first phase a cross-sectional research design was used and in the second phase an experimental research (interventional) design was used

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Metformin gastrointestinal adverse effects

Interventions
The first phase is a quantitative study in which a cross sectional research design was used. In this study patients having type 2 diabetes using metformin of different doses (500 mg, 850 mg and 100 mg) were considered. Patients having symptoms of metformin induced gastrointestinal problems were noted. The gastrointestinal symptoms induced by metformin were linked with dose, age, gender, frequency and way of intake of metformin. Data was collected from the patients by visiting the outpatient departments of different government and private hospitals.

In the second phase of the study an experimental design was used. In this phase patients having metformin induced gastrointestinal problems were divided into three groups (convenience

sampling was used). Each group consisted of 20 participants. The participants were subjected to PPIs in order to see the effectiveness of proton pump inhibitors such as omeprazole and pantoprazole. The first group of participants were subjected to omeprazole 40 mg. Similarly the second group was subjected to pantoperazole 40 mg. In this phase the initial symptoms of the patient were recorded and then after intervention the level and severity of the symptoms was again checked by directly interviewing the participants on their follow-up and recorded. Their blood sugar levels were also noted. In this way the effectiveness of the medicine is checked. The third group of the patients were subjected to non-pharmacological treatment i.e. take metformin during meals and the outcomes are recorded. The total duration of treatment with PPIs of each patient was one month and after one month patients were followed up.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omeprazole, pantoperazole, metformin

Primary outcome measure
GI symptoms measured by interview at baseline and 1 month

Secondary outcome measures
Blood sugar level measured at baseline and 1 month

Overall study start date
01/05/2017

Completion date
30/12/2017

Eligibility

Key inclusion criteria
1. Male and female aged 26-85 years
2. Patients diagnosed with Type 2 diabetes
3. Patients using metformin

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Total sample size 300. In the interventional phase of the study three groups were made, each group contained 20 patients.

Key exclusion criteria
1. Type 1 diabetes patients
2. Patients under 26 and older than 85 years
3. Patients who were not taking metformin
4. Patients on insulin therapy alone

Date of first enrolment
01/06/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
Pakistan

Study participating centre
Allied Hospital
Faisalabad
Pakistan
-

Study participating centre
Faisalabad Diabetic Center
Faisalabad
Pakistan
-

Study participating centre
Diabetic Institute Pakistan
Lahore
Pakistan
-

Sponsor information

Organisation

Lahore College for Women University

Sponsor details
Jail Road
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54000

Sponsor type
University/education

ROR
https://ror.org/02bf6br77

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
30/12/2018

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			16/08/2022	Yes	No