ISRCTN14518136 https://doi.org/10.1186/ISRCTN14518136

Determination of capillary blood concentrations of the oral antidiabetics metformin and/or sitagliptin in dried blood spots

Submission date
27/07/2016

Recruitment status
No longer recruiting

Registration date
28/07/2016

Overall study status
Completed

Last Edited
01/02/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes a person's blood sugar (glucose) level to become too high. Many patients with type 2 diabetes take the drugs metformin and/or sitagliptin to control their blood glucose levels. Although these medications are frequently prescribed it is widely unknown which typical blood levels of these drugs are found under "real-life" conditions, i.e. in patients taking additional other drugs such as blood-pressure lowering drugs or in patients with decreased kidney function. Knowledge of the blood levels of metformin and/or sitagliptin in a big group of patients might allow us to identify factors that influence those levels. The aim of this study is to determine the blood levels of metformin and/or sitagliptin in patients with type 2 diabetes, and to find factors which might influence those levels.

Who can participate?
Patients older than 18 with type 2 diabetes treated with metformin and/or sitagliptin

What does the study involve?
The participants' blood levels of metformin and/or sitagliptin are determined using a new approach which requires a small amount of blood obtained by finger pricking. The blood samples are collected in community pharmacies in Germany. The blood is spotted onto a filter paper and dried, then sent to the University of Würzburg for analysis of the drug levels.

What are the possible benefits and risks of participating?
If unusually high or low blood concentrations of metformin and/or sitagliptin are found, then the participant will be informed via the participating pharmacy. The patient can then contact his/her physician who might determine appropriate measures. In future, the results of this study might help to simplify and/or improve diabetes treatment. There are no particular risks associated with participating in the study. The procedure involves finger pricking and collection of capillary blood similar to the procedure for routine blood glucose measurement. This should be familiar for patients with type 2 diabetes.

Where is the study run from?
Universität Würzburg (Germany)

When is the study starting and how long is it expected to run for?
August to December 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Petra Högger
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
016/1525

Study information

Scientific Title
Cross-sectional study to determine real-life concentrations of metformin and/or sitagliptin in patients with type 2 diabetes in dried blood spots

Study objectives
Typical real-life blood concentrations of metformin and/or sitagliptin, e.g. in patients under polypharmacotherapy, are widely unknown and might be dependent on kidney function and/or

co-medication regimes. The aim of this study is to determine the real-life concentrations of metformin and/or sitagliptin in patients with type 2 diabetes in dried blood spots, and to find potential co-variates which might influence the concentrations, such as estimated kidney function or co-medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
International Review Board/Independent Ethics Committee Freiburg, 04/07/2016, ref: 016/1525

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Capillary blood of type 2 diabetic patients will be collected in participating community pharmacies. The blood will be spotted on a filter paper, dried and sent for analysis of metformin, sitagliptin and creatinine concentrations. Concentrations will be analysed in relation to the estimated kidney function using the Cockroft-Gault formula.

Intervention Type
Other

Primary outcome measure
Metformin and/or sitagliptin concentrations in capillary blood samples using the dried blood-spot technique

Secondary outcome measures
Potential co-variates which might influence the concentrations such as estimated kidney function or co-medication

Overall study start date

01/08/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients with type 2 diabetes mellitus under therapy with metformin and/or sitagliptin
2. Patients older than 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Target number: 250 participants

Key exclusion criteria
Patients with an infective disease

Date of first enrolment
01/08/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Germany

Study participating centre
Coordinating centre: Universität Würzburg
Institut für Pharmazie und Lebensmittelchemie
Am Hubland
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Sponsor information

Organisation
Universität Würzburg (Germany)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03pvr2g57

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of the study, including a detailed description of the study procedures, are planned to be published after finalization of the study and analysis of all samples.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	01/02/2019	Yes	No