

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

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| Submission date 27/07/2016 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 28/07/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 01/02/2019 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Other

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 Cockcroft-Gault formula.

Intervention Type

Other

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Würzburg

Germany

97074

Sponsor information

Organisation

Universität Würzburg (Germany)

ROR

<https://ror.org/03pvr2g57>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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 |