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Patient real-world handling of protein medications

Submission date 22/09/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/09/2023	**Overall study status** Completed	
Last Edited 23/06/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of this study is to understand better what happens to people's medicines once patients have collected them from a pharmacy or they have been delivered to the patient at home. The researchers are particularly interested in what happens to a group of medicines called protein medicines which are used to treat a wide number of health conditions (for example insulin in diabetes, some treatments for inflammatory conditions, skin conditions and other health problems). They are interested in protein medicines in particular because these medicines may be more prone to being affected by how and where they are stored and how they are transported. Using a credit-card-sized smart label containing sensors, which will be attached to medication packaging, this study will investigate how much light and moisture the medicine is exposed to as well as what temperature, movements and vibrations it experiences during normal storage and handling by patients.

Who can participate?
Adults aged 18 years and over who are currently prescribed protein medications for administration outside a healthcare setting

What does the study involve?
Participants will be given an activated smart label to attach to their protein drug packaging. This will record movement, humidity, temperature and light until the patient uses the drug. The label will then be returned to the study team where the data will be extracted and analysed.

What are the possible benefits and risks of participating?
There are no risks to taking part. Benefits will be for future users of the medication in the form of better education on protein drug handling for patients and healthcare providers.

Where is the study run from?
MEMO Research, University of Dundee based in Ninewells Hospital and Medical School, Dundee (UK)

When is the study starting and how long is it expected to run for?
February 2023 to June 2025

Who is funding the study?
Innovative Medicines Initiative (Belgium)

Who is the main contact?
Prof. Isla Mackenzie, memo-info@dundee.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Isla Mackenzie

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331245

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2-062-23, IRAS 331245

Study information

Scientific Title
Patient real-world handling of protein medications – a smart label study

Study objectives
The aim is to gain information about how protein medications are handled by patients during collection, storage and use at home. This will improve our understanding of environmental

stressors such as temperature, shock, humidity and light that protein medications may be exposed to during normal transport, storage and use by patients. Data will be collected by attaching smart labels with sensors that monitor light, humidity, temperature and accelerometry to patients' medication packets. Patients will also be asked to complete a short diary to record any events that may occur such as inadvertent exposure to high or low temperatures, or dropping of medication.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/09/2023, East Midlands - Nottingham 2 Research Ethics Committee (Health Research Authority, Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8169, +44 (0)207 104 8278, +44 (0)208 104 8051; nottingham2.rec@hra.nhs.uk), ref: 23/EM/0207

Study design
Single-centre questionnaire and observational study

Primary study design
Observational

Secondary study design
Questionnaire

Study setting(s)
Home, Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Cardiovascular disease, diabetes, rheumatology and gastroenterology

Interventions
The study will involve collecting data on environmental stressors using a participant diary and smart labels attached to medication packaging over a period of around 1 month.

Intervention Type
Other

Primary outcome measure
Medication movement, humidity, temperature and light exposure measured using smart label sensors following medication collection for a period of up to 1 month

Secondary outcome measures
There are no secondary outcome measures

Overall study start date

20/02/2023

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Adults >=18 years old currently prescribed protein medications for administration outwith a healthcare setting
2. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
20

Total final enrolment
12

Key exclusion criteria
1. Patients requiring administration of their medication in a hospital setting
2. Patients prescribed protein medications that are administered at intervals of greater than fortnightly

Date of first enrolment
02/10/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

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TASC, Ninewells Hospital and Medical School
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Research organisation

Funder Name
Innovative Medicines Initiative

Alternative Name(s)
The Innovative Medicines Initiative, Europe's Innovative Medicines Initiative, EU Innovative Medicines Initiative, IMI

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal and presentation at scientific conference

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	25/07/2023	25/09/2023	No	Yes
Participant information sheet	version 2	18/09/2023	23/06/2025	No	Yes