ISRCTN17179811 https://doi.org/10.1186/ISRCTN17179811

# Patient real-world handling of protein medications

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

### Integrated Research Application System (IRAS)
331245

### Protocol serial number
2-062-23

# 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

### Primary study design
Observational

### Study design
Single-centre questionnaire and observational study

### Study type(s)
Other

### 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(s)
Medication movement, humidity, temperature and light exposure measured using smart label sensors following medication collection for a period of up to 1 month

### Key secondary outcome(s)
There are no secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
All

### 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
United Kingdom

Scotland

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

## Sponsor information

### Organisation
University of Dundee

**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

**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 |