Participant Information Sheet

A Phase III multi-stage randomised clinical trial to determine the effects of weight loss, induced by Tirzepatide, in adults with active idiopathic intracranial hypertension

Summary of the IIH-Advance Trial

We would like to invite you to take part in our research study. Taking part is voluntary. Before you decide, we would like to give you information about why the research is being done and what it involves. Please take time to read this information sheet. Feel free to talk to others about the trial if you wish. If you decide not to take part, your usual care will not be affected.

- This trial will look at how weight change, using a weight loss drug, affects women and men with Idiopathic intracranial hypertension (IIH) and papilloedema.
- The trial will also look at the effects on IIH after the weight loss drug is stopped. We expect there will be weight regain, but we don't know if active IIH will come back.
- Previous research shows weight loss can help reduce brain pressure. In this trial we will focus on things that are more meaningful to patients such as quality of life.
- Everybody in the trial will get the weight loss drug for 6-12 months (subject to keeping to the trial plan).
- The weight loss drug we will use is called Tirzepatide (also called Mounjaro).
- The trial will use online appointments, with 1-4 visits to a local Specsavers.
- Please read on or visit our online information tool for more information:

https://iih-advance.digitrial.com

Why have I been invited?

We are inviting you to take part because you have been diagnosed with IIH, are 18 or older and have increased body weight.

You may be able to take part in IIH-Advance if:

- we can confirm your IIH is active and
- you have swelling of the nerve at the back of the eye (called papilloedema)

You need to have papilloedema as this is a useful way to monitor brain pressure. If you no longer have papilloedema you will not be suitable for the trial as we could not check for improvement.

Do I have to take part?

No, this is up to you. Taking part is voluntary. You do not have to take part if you do not want to, and this will not affect the care you receive. We are giving you this information so you can consider it carefully before you choose. Feel free to discuss it with friends and family. If there is anything that is not clear, please speak to a member of the research team (contact details at the end).

Why are we doing this research?

IIH is a serious condition that results in raised intracranial (brain) pressure. IIH is rare and affects about 1 in 20,000 people in the UK. The condition most often occurs in women living with obesity. The most common symptoms are disabling headaches and visual problems. To have a confirmed diagnosis of IIH, you will have had swelling of the nerve at the back of the eye (papilloedema) and a high lumbar puncture pressure (over 25 cmCSF).

Treatment for IIH is limited. There are no licenced drugs, although some people with IIH take acetazolamide. Weight loss reduces brain pressure and improves headaches and vision. We don't know the best way to achieve weight loss for IIH. Previous studies have tried diets or surgery.

Now, drugs have started being used in the NHS that can lead to meaningful weight loss. These weight loss drugs may be able to treat people with IIH. They are increasingly being sought by patients. Their use in IIH is not well understood though. In IIH-Advance, we are looking at how much weight loss is needed to improve IIH, and if there is a risk of IIH returning if weight loss is reversed.

Which drug are we using to help with weight loss?

We are using a drug called Tirzepatide. This drug is used in the NHS to treat obesity. Studies have shown that in people living with obesity it can lead to more than 10% weight loss in 6 months.

What would taking part involve?

All the trial appointments in IIH-Advance will be done online. The only visits that you will need to attend in person are visits to Specsavers to have eye scans.

There are four stages to IIH-Advance:

- The first stage is screening. Here we will see if you are eligible to take part. This will last a month.
- The second stage will last 6 months. You will either take the medication Tirzepatide or follow your usual NHS treatment. This will be decided by a fair process called **randomisation**.

- The third stage will last another 6 months. If you continue into this you will either take Tirzepatide or follow your usual NHS treatment.
- The last stage will be another 6 months. If you have not yet taken Tirzepatide, you will take it for this last stage.
- There will be monthly appointments throughout, with longer appointments every 6 months – up to 19 online appointments in total, and about an hour every month for online appointments.

Table 1: IIH-Advance month by month

Screening month	Month 0	Month 1-2	Month 3	Month 4-5	Month 6	Month 7-11	Month 12	Month 13-17	Month 18
Screening 1 hour appointment	**Main 1 hour appointment**	**Monthly 30-minute appointments**	Sleep tracker sent and sample kit provided	**Monthly 30-minute appointments**	Sleep tracker sent and sample kit provided	**Monthly 30-minute appointments**	**OCT scan at Specsavers**	**Monthly 30-minute appointments**	**OCT scan at Specsavers**
Headache diary started	Tirzepatide OR standard care		Take and send samples		Take and send samples		**Main 1 hour appointment**		**Main 1 hour appointment**
OCT scan at Specsavers			**Monthly 30-minute appointment**		**OCT scan at Specsavers**		Tirzepatide OR standard care		
Sleep tracker sent					**Main 1 hour appointment**				
Sample kit provided: take and send samples					Tirzepatide OR standard care				

Screening to see if you can take part

If you are interested in taking part in IIH-Advance and send us your contact details through our expression of interest form, we will invite you to an online screening appointment.

This appointment is to see if you are eligible to enter the main trial. We will ask you to:

- Provide a letter from a healthcare professional confirming your diagnosis of IIH with papilloedema. You can get this from the NHS app or you can give a copy of your last clinic letter from your hospital doctor.
- Submit your height and weight so that we can work out your body mass index (BMI). First you will do this with your own scales, but if you continue into the trial we will send scales so everyone measures using the same model. They won't need to be sent back.
- To take part in the trial your BMI needs to fall into one of the categories below:
    - Your BMI is 30.0 kg/m^2 or more.
    - Your BMI is 27 kg/m^2 or more, and your IIH started following a period of weight gain.
    - Your BMI is 27 kg/m^2 or more, and you are from an Asian, Middle Eastern, Black African or African Caribbean family background.
- If it looks like you may be eligible, you will be asked to electronically sign an Informed Consent Form. We will then arrange an OCT scan to confirm that you can join the main trial. You should only do this if you are happy that you understand the trial and are happy to have the OCT scan. A copy of your consent form will be sent to you by email.
- A first treatment allocation appointment will be provisionally booked with the researcher in about a month.
- You will be asked to start keeping a headache diary so the trial doctor can discuss your headache progress with you.

Eye scan at Specsavers

- We will arrange for you to have an eye scan at a Specsavers store near to you. This is called optical coherence tomography, or OCT. It usually takes about 10 minutes. You may have had an OCT scan before if you have been diagnosed with papilloedema. The OCT report will be sent to the research team to work out if you have active enough papilloedema to take part.
- If you don't have active papilloedema you won't be able to take part. We will keep the anonymous data though and we will call you to let you know.
- There are no known risks or side effects for having an OCT scan.

Research samples

If you are eligible to join the trial after the research team have checked your OCT scan, they will contact you to check you are happy to continue. If you are, they will send you a pack. This will contain scales, a tape measure for your waist and neck, a wearable tracking device and a kit to take blood, saliva, urine and stool samples.

The wearable tracking device is to track your sleep for two weeks before your first treatment allocation appointment. We are interested in how IIH can affect sleep.

The samples involve:

- Collecting a small amount of blood (1 ml, or about 40 drops of blood) This will be done by yourself at home using a special kit that will sample drops of blood from your finger.
- Collecting saliva using a kit that we will provide.
- Collecting urine for 24 hours and sending us around 20ml back – about 4 teaspoons.
- Collecting a small sample of your stool using a kit that we will provide.
- There are a set of videos to show you what is involved: https://iih-advance.digitrial.com/resources
- The samples should be posted back to us before your first treatment allocation appointment.

Pregnancy test

If you are female and of childbearing potential, you will be asked to do a urine pregnancy test before you enter the trial. We will send you this. You will have to show the researcher during the first treatment allocation appointment – if it's not clear by video we'll ask you to send a photo.

First treatment allocation appointment

If you are eligible to join the trial after you've had the OCT scan then we will confirm your first treatment allocation appointment. At this appointment, the research team will check you are happy to continue. They will collect some more information from you. This will include questions in the form of interviews during the online appointment. This call might take up to an hour.

Some of the questionnaires cover topics that some people might find sensitive. If you would like to discuss this with the trial researcher they are happy to help if you find it difficult at any time. You can also find information about resources local to you at https://www.nhs.uk/nhs-services/mental-health-services/.

You will be given a trial ID number and then you will be allocated to either the Tirzepatide medication or standard of care group by a process called **randomisation**. There is a 50:50 chance of either. If you are allocated to Tirzepatide the trial doctor will prescribe the medication for delivery to your home. If you remain on standard of care you will continue with the care provided by your usual NHS team.

What is randomisation?

When we don't know which treatment option is best, we need to compare them. In this case, we know Tirzepatide will lead to weight loss, but we aren't sure about the level of weight loss needed to help your IIH or what happens with your IIH if you stop taking it.

To make a fair comparison we use 'randomisation'. Most large trials use randomisation. This means everyone taking part is randomly allocated to the treatment choices in the trial. Neither you nor your doctor choose which group you will be allocated to. This helps avoid bias – like personal preferences affecting how people are treated or assessed. If the groups of people receiving each treatment are similar, then any differences in the results should be because of the treatment. Randomisation makes results more reliable.

- In the IIH-Advance trial, there is an equal chance of being allocated to one of two groups for the first 6 months, Tirzepatide or standard of care.

- After 6 months we will check your vision and other symptoms. If you are eligible to continue you will be randomised again, to Tirzepatide or standard of care for another 6 months.
- For the last 6 months, people who have received Tirzepatide will be followed up with standard of care so we can see if your weight and symptoms change.
- Anyone who hasn't received Tirzepatide yet will be prescribed it so everyone will receive Tirzepatide for at least 6 months as part of the trial.

Monthly online appointments

If you enter the main trial then you will have up to 15 half hour monthly appointments over the next 18 months. You will:

- Give the research team details about you and your medical history.
    - They will ask you questions about your IIH, how you are feeling, any side effects and check that you are doing well.
- Measure your weight during the appointment.
- Discuss your headaches over the last 28 days.

We will follow your progress carefully during the trial. Every month after you enter the trial, whether you are taking Tirzepatide or not, a member of the research team will contact you by video call to monitor your health and see how your IIH is going. We will also ask you to measure and record your weight using the weighing scales we have sent you. You will need to submit a picture of the scales showing your weight each month (or you can show us your weight on the scales during the video call). You need to attend these appointments to continue in the trial, and we can't prescribe next month's treatment without the monthly checkup first.

If you are allocated Tirzepatide and attend your monthly appointment, a new prescription will be sent to you every month. Tirzepatide is delivered using an injector pen and we will show you how to use this. We ask you to not throw away your injector pen when it is empty. This is so we can ask to see the empty pens during the monthly video calls.

3 and 6 month samples

We will ask you to send us blood, saliva, urine and stool samples again at 3 months and 6 months. We will also send out the activity tracker again to wear for 2 weeks before your 3 and 6 month appointments. You will be sent everything needed to collect these samples and return them to us.

Second treatment allocation appointment

After 6 months we will arrange for another eye scan at Specsavers. The research doctor will check the scan to see if your papilloedema are improving and then you will have a longer appointment with your researcher.

During this call, you will repeat most of the interviews and questionnaires from the first appointment. The appointment may take around 60 minutes.

We will check your IIH and you may be randomised again to either 6 months of Tirzepatide or standard of care:

- If you were taking Tirzepatide and your papilloedema are improving, you will be randomised again.

- If you were not taking Tirzepatide and your papilloedema are not improving, you will be randomised again.
    - If you are randomised again you will have a 50:50 chance of receiving Tirzepatide or standard of care for the next 6 months.
    - If you are randomised again, you will continue with monthly follow-up appointments until the third treatment allocation appointment at 12 months.
- If you were taking Tirzepatide with no improvement, or if your papilloedema have improved without taking it, then you will not be randomised again. You'll have a short checkup 5 weeks after stopping Tirzepatide and then leave the trial.
- Some people will regain weight after stopping Tirzepatide. If you were taking Tirzepatide in the first 6 months but have not been randomised to take it in the second 6 months, the IIH-Advance trial will study the effects of stopping Tirzepatide. This could include weight gain.

Third treatment allocation appointment

After another 6 months we will arrange for another eye scan at Specsavers. The trial doctor will check the scan to see if your papilloedema are improving. Then you will have a longer appointment with your researcher.

During this call, you will repeat most of the interviews and questionnaires from the first appointment. The appointment may take around 60 minutes.

- Everybody who has not yet been taking it will be prescribed Tirzepatide for the final 6 months of the trial. Then there will be online monthly follow-up appointments as above until the final trial appointment.
- Everybody else will leave the trial. You'll have a short checkup 5 weeks after stopping Tirzepatide if you have been.

Trial end appointments

- If you are taking Tirzepatide after the third treatment allocation appointment you will have a longer appointment with the researcher at 18 months, as you did at 6 and 12 months. This may take around 60 minutes. This is so we can review your overall progress during the trial.
- Five weeks later you will have a final checkup appointment with the researcher and then finish the trial and continue with standard NHS care.
- Unfortunately, we can't continue to provide Tirzepatide after your involvement in the trial has ended. If you think it would benefit your health further to continue taking Tirzepatide, please contact your GP.

Focus group

We will ask 8-10 people to attend one of two optional online focus groups, to discuss experiences of weight management services in the NHS. We will ask if you are happy to be contacted for this on the main consent form. If so, you will be contacted and given a separate information sheet.

Is the treatment safe?

Along with their usual effects, most medicines can cause unwanted side effects, although not everyone experiences them. Before starting Tirzepatide, you should read the manufacturer's printed

information leaflet provided inside the medication box. The leaflet will give you more information about the medication and a full list of side effects which may be experienced. If you fall below a BMI of 20 the doctor may decide to stop your medication for safety reasons.

You should also let your treating doctor or surgeon know you are taking Tirzepatide if you are due to have sedation or general anaesthetic for an operation.

Tirzepatide

Tirzepatide is a medication used to promote weight loss in adults. The dose of Tirzepatide is increased as you take it over the six months. It is taken by weekly self-injection. There are some mild risks to self-injection (up to 1 in 10 people) which include redness, warmth, swelling, bruising, minor pain and irritation.

You should also note that when treatment with Tirzepatide is stopped we expect there to be some weight regain in most cases.

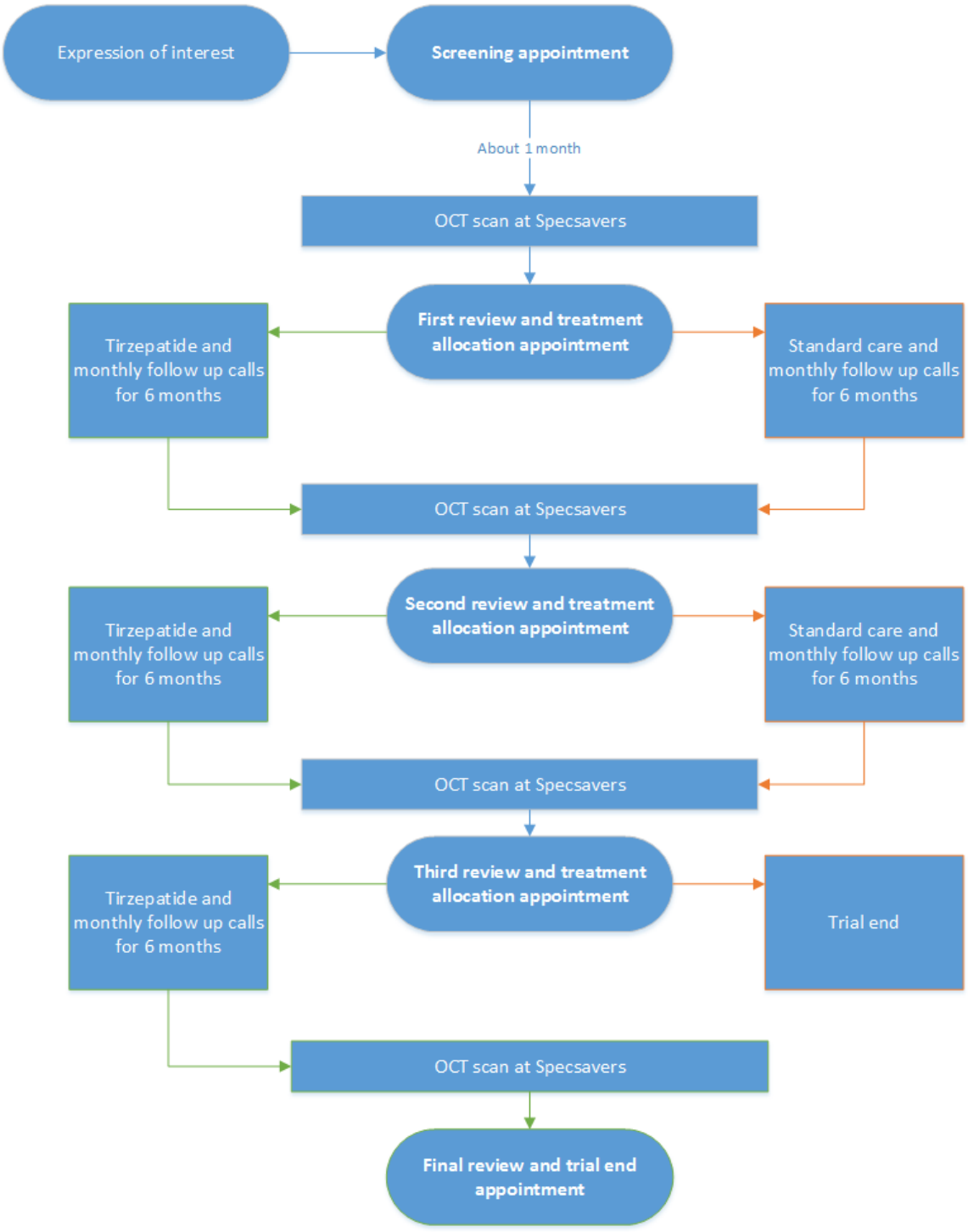
The most common side effects of Tirzepatide may include: nausea (up to 1 in 5 people); diarrhoea, vomiting, constipation (around 1 in 10 people); indigestion, and stomach pain (around 1 in 20 people). They tend to improve as your body adjusts.

Low blood sugar is very common in patients with diabetes, and Tirzepatide can lower blood sugar. You cannot enter the trial if you have diabetes and are taking medication for it.

Tirzepatide may cause serious side effects, including:

- **inflammation of your pancreas (pancreatitis).** You should stop using Tirzepatide and contact your medical team if you have severe pain in your stomach area that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **gallbladder problems.** Tirzepatide may cause gallbladder problems, including gallstones. Some gallstones may need surgery. Contact your medical team if you have symptoms, such as pain in your upper stomach, fever, or yellowing of the skin or eyes (jaundice).
- **kidney problems.** In people who have kidney problems, diarrhoea, nausea, and vomiting may cause a loss of fluids (dehydration). This may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.
- **serious allergic reactions.** Stop using Tirzepatide and get medical help right away if you have any symptoms of a serious allergic reaction. These include swelling of your face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or a very rapid heartbeat.

Figure 1: Going through the trial



Pregnancy and breast-feeding

Pregnant women are advised not to take Tirzepatide, so we can't allow you to join the trial if you are pregnant or planning to become pregnant. We also ask that you stop breastfeeding if you are. Tirzepatide is not recommended during breastfeeding because we don't know if it is safe for the nursing infant.

Female participants of childbearing potential will be asked to show the research team a negative urine pregnancy test at the time of joining the trial. We also ask female participants of childbearing

potential to do a pregnancy test at the second and third treatment allocation appointments. Female participants must use effective contraception during and for 5 weeks after stopping treatment.

If you become pregnant during the trial, please tell us. Your research team will need to stop your treatment if you were allocated Tirzepatide and will advise on what to do. You will still be followed up in the trial and asked to complete the interviews with the researcher.

Tirzepatide may affect reduce the efficacy of oral contraceptives, so it is advised that female participants using an oral contraceptive should add a barrier method of contraception or switch to a non-oral contraceptive method.

How will I receive the medication?

Tirzepatide will be delivered to your home free of charge. You should take your trial medication as directed and continue all other medications as usually advised.

Will I get paid for taking part?

No, but we can reimburse your travel expenses to your local Specsavers store for any trial appointments. Please speak to a member of the research team for more details. Please make sure you keep your receipts if you would like to be reimbursed.

What are the possible benefits of taking part?

In those participants that lose weight, we would expect IIH to improve but it might not happen in everyone. We don't know how much weight will be lost and how much it might improve IIH.

It is known that in some people weight gain will happen again when they stop Tirzepatide. Within 12 months of stopping the drug some patients may regain two thirds of their lost weight. We don't know if this will make your IIH get worse again. Whilst there may be no ongoing benefits to you, the aim is to improve the longer-term care for people with IIH. The trial will help us find out if Tirzepatide is a useful medication for weight loss in patients with IIH.

What are the possible disadvantages and risks of taking part?

Like any medication, Tirzepatide can have side effects as detailed above, so the research team will monitor you closely at your appointments. If you have concerns during the trial, please contact the research team. If you become unwell during your treatment, seek medical help and do let the research team know.

How long will I be followed up for?

We would like to follow you up using central NHS data for up to 10 years after the end of the trial. To do this, University of Birmingham will send your identifying details (name, date of birth, NHS number, gender) to NHS England. NHS England will use these to match your details to national NHS data (such as Hospital Episode Statistics, which records hospital admissions, or information routinely collected during GP visits, such as prescriptions) and securely provide University of Birmingham with this information. We'll only use this data for the IIH-Advance trial. You can withdraw this permission at any time, and this will not affect your medical care.

What will happen to my treatment when the research trial stops?

After the trial you will continue with your usual NHS care. We cannot provide Tirzepatide after the trial.

PART 2 – ABOUT HOW WE CONDUCT RESEARCH

Who is organising, insuring and funding the trial?

The trial is sponsored by the University of Birmingham. This means the University has certain legal and ethical responsibilities for the trial. It is being coordinated by Birmingham Clinical Trials Unit and it is funded by the Sir Jules Thorn Charitable Trust. The Chief Investigator is Professor Alexandra Sinclair, Professor of Neurology at the University of Birmingham.

The University of Birmingham arranges clinical trial insurance which is renewed annually and provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial. The insurance may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

How have patients and the public been involved in this trial?

The trial has been developed with input from representatives from IIH UK (https://www.iih.org.uk/). The conduct of the trial is entirely in the hands of experienced researchers and no PPI group or lay person has any access to your personal healthcare records or is able to influence your treatment.

Who has reviewed the trial?

All medical research is looked at by an independent group of people who protect patient interests. This group is called a Research Ethics Committee. Before we asked any patients to join, the trial was reviewed and approved by London - Central Research Ethics Committee.

What happens if new information becomes available?

Sometimes we get new information about a treatment being studied. If this happens, a member of the research team will tell you and discuss whether you should continue in the trial. You will have the option to decide whether to continue if you are happy to.

What if I no longer want to take part?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.

How will we use information about you?

We will need to use information from you for this research project. This information will include the below:

When	What data will be collected
• Expression of Interest	• Full name (first, middle & surname) • Contact details: email address, mobile number
• Screening appointment	• Full date of birth, gender, NHS number, GP details (optional) • Address
• Treatment allocation appointments	• Relevant medical history including weight • Current medications • Interviews and questionnaires completed during this visit

• Follow up appointments	• Weight, medication use • Interviews and questionnaires completed during this visit
• OCT scan	• OCT scan report including full name

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

As sponsor of this research. University of Birmingham is responsible for looking after your information. We will keep all information about you safe and secure:

- Your contact details will be stored on secure University of Birmingham servers. If you do not proceed into the trial they will be stored but made inaccessible to anyone.
- All information collected from you will be securely stored and kept strictly confidential according to the Data Protection Act 2018 in the same way as your usual medical records.
- Information for this trial will be recorded and stored on our secure University of Birmingham servers.
- Specsavers will send OCT eye scan reports by email to the trial research team using the same secure email they would use to send a referral to the NHS.
- Your personal data will not be used by Specsavers to contact you for any reason not related to this research. This includes for any commercial or advertising purposes. If you are already a Specsavers customer, your existing privacy choices will be followed.
- We will have to send the pharmacy your personal details as required to deliver medication (name, date of birth, phone number, email address and address). This will be managed on a secure prescribing portal set up specially for the trial.
- We will have to send Specsavers your personal details as required to arrange OCT eye scans (name, date of birth, phone number, email address and address). This will be done by secure email.

We may share or provide access to data about you outside the UK for research related purposes to:

- Analyse your samples.
- Request expert analysis of specific sections of data, such as the activity tracker data.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Universities and other academic researchers
- Commercial laboratory providers if needed to analyse your samples

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

How will we use information about you after the trial ends?

We will keep your trial data for a maximum of around 3 years after the trial end. The trial data will then be anonymised and securely archived. After 10 years it will be destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- if you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records if you have consented to this. If you do not want this to happen, tell us and we will stop
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our HRA leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team, or
- by contacting the University of Birmingham Data Protection Office:
    - The Data Protection Office, Legal Services, The University of Birmingham, Birmingham B15 2TT. Email: dataprotection@contacts.bham.ac.uk. Telephone: 0121 414 3916

What will happen to the samples I give?

Your samples will be sent for processing and storage in the University of Birmingham Biomedical Sciences Laboratory. Your data will not be linked in any identifiable way. We will measure hormones in the blood and urine, and study genetic material in the blood and saliva samples. We will also measure proteins related to inflammation and migraine pain in the blood and saliva samples. Finally, we will examine the bacteria in the stool samples to study the interaction between gut bacteria and IIH. The test results will remain confidential: you will not be given the results of these tests.

Your samples will be kept for 2 years after the end of the study to allow time for the samples to be analysed. After this, excess samples will be stored in the University of Birmingham Human Biomaterials Resource Centre biobank or be destroyed. Some samples might be sent outside of the UK or EU for analysis.

We will also ask you if you specifically consent for us to keep your samples for possible future ethically approved research. Again, if you permit this then no personal information will be sent with them and they will only be identifiable with a sample code. This is optional and whether you choose to permit this will not affect you taking part in the IIH-Advance trial.

What if something goes wrong?

We do not expect any problems because of your participation in this research. If you have a concern about any aspect of the trial, you should ask to speak to a member of the research team who will do their best to answer your questions.

If you wish to complain about any aspect of the way you have been approached or treated during this trial, the normal NHS complaints mechanisms will be available to you. Copies of these guidelines are available on request. If you wish to complain about how you have been treated during this trial please contact the Patient Advice and Liaison Service (PALS) or the Complaints Team at your local hospital. The contact details can be found via this website: https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/

Will my GP be informed of my involvement?

We will inform your GP that you have joined the trial if you agree to it, and if you have been allocated to Tirzepatide at the second and third treatment allocation visits.

Who can I contact for further information?

Thank you for taking the time to read this information sheet and for considering taking part. If you'd like further information or would like to speak to someone about the trial please contact:

Name	
Job title	
Contact Details	

Alternatively, you can contact the IIH-Advance trial team:

IIH-Advance trial office

Birmingham Clinical Trials Unit

Public Health Building

University of Birmingham

Edgbaston

B15 2TT

Email: IIH-Advance@trials.bham.ac.uk