



Patient Information sheet for investigation, treatment, or procedure with (HS4-20) M3, for respiratory or other administration

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following explanation of why we are conducting the research and what you can expect if you take part. First of all, participation is entirely voluntary.

Please read the following information and please let us know if any of this is not understandable or if you have any questions.

1. Hypo-Stream Lt has been developing a medicinal physiologic aqueous chlorine wash, drench, rinse and aerosol that is based upon the natural endogenous chemistry of human white blood cells.
2. The compounds that have been developed are very similar to compounds that were used for washing infected wounds, gunshot wounds and infected burns of injured patients for many decades and are extremely safe.
3. The result of the research is a technology we call M3. M3 can be given to patients as a wash or a mouth rinse or inhaled into the lungs as an aerosol.
4. Hypo-Stream has worked formally with the UK medicines regulator (MHRA) and submitted data from existing research and our research to show that our formulations are of a pharmaceutical standard, safe and of benefit to patients. Hypo-Stream has also worked with the European Medicines Agency (EMA) and the equivalent agency in the USA (FDA). This is on a formal basis and documented fully.

The Hypo-Stream M3 medicinal wash and rinse has been used safely for hundreds of patients without adverse effects and the risks are extremely low.

The purpose of this study, which you may choose to take part in, is to help collect more information on the safety and possible benefits of the M3 medicine and also to help identify any risks associated with its use.

Study Title

Study of safety of inhaled HS4-20 aerosol of physiologic aqueous chlorine.

Why have I been invited?

☐ You have been invited to take part because you are healthy. You might have been invited to take part because you have a risk of contracting covid-19. or because they are healthy individuals)

☐ We are intending to enrol up to 20 healthy individuals and up to 50 individuals who are at risk of developing covid-19

Do I have to take part?

☐ No. Taking part is entirely voluntary. Also, you can withdraw if you later change your mind, without giving a reason;

What will happen to me if I decide to take part?

If you take part, you will be expected to provide your own nebuliser (we can recommend Omron Comp-Air nebuliser available from Amazon.com).

We will provide you with a supply of HS4-20 concentrate and instructions on how to dilute this and use the diluted HS4-20 to fill the reservoir of the nebuliser.



You will then be asked to breath the nebulised vapour for twenty minutes every day. This might be increased to twenty minutes four times a day (every six hours).

We would expect you to be involved for as long as you wish, but at least for seven days.

We will collect information from you face to face or by telephone or email questionnaire.

If you are having regular PCR tests for covid-19 we request that you send us copies of the test results and give permission for Hypo-Stream to examine, interpret and collect the results. Hypo-Stream will use the results to communicate with academic, regulatory and commercial organisations and you will need to give permission for Hypo-Stream to use the data in this way.

What should I consider?

There are no conditions which exclude you from taking part.

You should continue taking all your regular medicine regardless of whether they are prescribed or over the counter medicines.

You are free to participate even if you are involved in other studies.

Talking part in the study has no impact on your requirements for contraception.

Are there any possible disadvantages of taking part?

As of now, we are not aware of any unwanted effects, side-effects or adverse reactions to the topical (on the surface) administration of HS4-20 either on skin or inhaled as a vapour.

We have no testing procedures or blood test requirements unless this is specific to the investigation.

What are the possible benefits of taking part?

We know that the inhaled HS4-20 is an effective agent in killing Sars-Covid-2 (covid-19 is one example of Sars-Covid-2).

We know that HS4-20 has an anti-inflammatory action when administered to skin, but we do not know if HS4-20 that is inhaled as an aerosol has an anti-inflammatory action.

We believe that inhaled HS4-20 might provide a protection against Covid-19 infection and also treat the symptoms associated with this viral infection.

Will my General Practitioner/family doctor (GP) be informed of my participation?

We do not routinely inform your GP that you are taking part in a safety study.

We do not routinely inform your GP if you are involved in a study to assess prevention of Covid-19 infection or illness.

If you choose to take part please feel free to let your GP know you are participating in this study and if at anytime during this study you see a GP or other doctor please let them know you are participating.

Will my taking part in the study be kept confidential?



Yes. In our data collection, you will be assigned a number for the purposes of record keeping.

Data is kept secure on Hypo-Stream secure data management systems that are password protected. GDPR laws apply to your data.

Will I be reimbursed for taking part?

No, although all the medicines involved HS4-20 is provided free of charge.

No reimbursement for travel is made.

What will happen to my data?

Data is collected and held, securely, by Hypo-Stream Ltd.

Data is kept secure on Hypo-Stream secure data management systems that are password protected. UK and EU GDPR laws apply to your data.

What will happen if I don't want to carry on with the study?

Participation is voluntary and you are free to change your mind at any time.

Please inform us that you wish to withdraw as we will wish to conduct a short review of how the treatment affected you and if you noticed any benefit or adverse event.

We are not collecting any samples or tissues, so there is no process required to manage these.

What will happen with the results of this study?

We intend to submit the results of this study to medicines regulators and they also may form part of a publication in an academic peer reviewed journal.

You will not be identified or identifiable in any submission to a regulator or in any published scientific paper.

If the results of the investigation are published, we will provide you with copies of the published work on request.

What if we find something unexpected?

Any unexpected event or finding will be managed via referral to the correct medical or surgical specialist or your GP.

Our team at Hypo-Stream comprises an experienced healthcare professionals.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached

or treated during the course of this study, you should contact <Myles Dakin at the Hypo-Stream Cambridge office Unit 9 Beech House, Melbourn Science Park, Melbourn, Cambridge SG8 6HB, 01763 261129, myles.dakin@hypo-stream.com

Who is organising and funding the study?

The study is funded and operated by the researchers of Hypo-Stream Ltd.

The study is sponsored by Hypo-Stream Ltd.

The clinical and analytical members of the Hypo-Stream team are unpaid.

Who has reviewed the study?

Hypo-Stream has a research and ethics committee led by the chief scientific officer (Professor Richard Aspinall) and chief medical officer (Dr Thomas Kenny). Richard was formerly Professor of translational medicine at Cranfield University and Thomas was formerly a director at NIHR.

Thank you for reading this information.



Thank you for considering taking part.

All documentation from MHRA, EMA is available on request from Myles Dakin who can be contacted at: Hypo-Stream Cambridge Office, Unit 9 Beech House, Melbourn Science Park, Melbourn, Cambridgeshire SG8 6HB

myles.dakin@hypo-stream.com
