TO BE PRINTED ON HEADED PAPER

<Insert GP name and address>

Date

Dear Doctor *Name*

Short title: STARFISH
Full title: A randomised controlled trial of STeroid Administration Routes For Idiopathic Sudden sensorineural Hearing loss

Trial information: IRAS: 1004878; REC ref: <insert>; EudraCT no.: 2022-000085-17

Patient Name:	<insert >	**DoB:**	< insert >
NHS Number:	<insert >		
Patient Trial Number:	<insert trial no.>		

I am writing to inform you that your patient has consented to take part in the STARFISH trial. This is a pragmatic, multicentre, assessor-blinded, parallel, 3-arm intervention superiority randomised controlled trial with an internal pilot.

The aim is to determine whether oral, intratympanic, or combined oral and intratympanic steroids provide the best first line treatment for idiopathic sudden sensorineural hearing loss (ISSNHL). ISSNHL is defined as a loss of sensorineural hearing occurring over a short (3 day) period, with no clear cause.

A copy of the Patient Information Sheet can be found at www.birmingham.ac.uk/STARFISH.

This participant has been randomised to receive the following intervention:

- **Oral steroid:** Prednisolone 1mg/Kg/day up to 60mg/day for 7 days.
- **Intratympanic steroid:** Dexamethasone given as three intratympanic (middle ear) injections 3.3 or 3.8mg/ml spaced 7±2 days apart.
- **Combined steroid:** Oral (Prednisolone) and intratympanic (Dexamethasone) as described above, with the first intratympanic injection occurring on day 1 of oral steroid use.

Participants in the trial will be followed up at 6 and 12 weeks following randomisation.

If you have cause to see your patient during the course of the trial and want to discuss any aspect of their management (e.g. treatment regimen, contraindications) please do not hesitate to contact us.

If you are informed of a pregnancy occurring in a female participant, please notify us as soon as possible.

STARFISH is coordinated by Birmingham Clinical Trials Unit (address below) and is sponsored by the University of Birmingham). The Co-Chief Investigators are Mr James Tysome, and Mr Matthew Smith, both at Cambridge University Hospitals NHS Foundation Trust. This trial is funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme (ref. NIHR131528) and approved by the <insert REC name>.

If you have any questions or would like more information, please contact us on the details provided below.

Yours Sincerely,

<Insert local contact name>
<insert phone number, email, address>

<insert PI name>
<Insert phone number, email, address>

Coordinating Centre:
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