

# DEPARTMENTAL INDUCTION



A randomised controlled trial of **ST**eroid **A**dministration  
**R**outes **F**or **I**diopathic **S**udden sensorineural **H**earing loss

# THE STARFISH TRIAL



**Local Principle Investigator:** XXX

**Local Associate PI:** XXX

**Funder:** National Institute for Health and Care Research (NIHR)

**Chief Investigators:** Matthew Smith and James Tysome

These slides are designed to help the local PI and aPI introduce the trial to the local department

*A separate, more detailed presentation is provided for those seeking inclusion on the delegation log*

## BACKGROUND



### Idiopathic sudden sensorineural hearing loss (ISSNHL):

- ❖ Incidence approximates 5-20 per 100,000
- ❖ Spontaneous recovery is seen in 32-65% of cases
- ❖ May go unrecognised or unreferred
- ❖ Functional and psychological impact on patients can be great
- ❖ *Steroid administration route was a high priority research recommendation from NICE*

# TRIAL OBJECTIVES



## Primary Objective:

- ❖ To establish the relative effects of oral, intratympanic or combined oral and intratympanic steroids on hearing recovery in ISSNHL, when used as first line management

## Secondary Objectives:

- ❖ To complete a health economic assessment of the different routes of steroid administration
- ❖ To use participant submitted data to explore the trajectory of hearing recovery

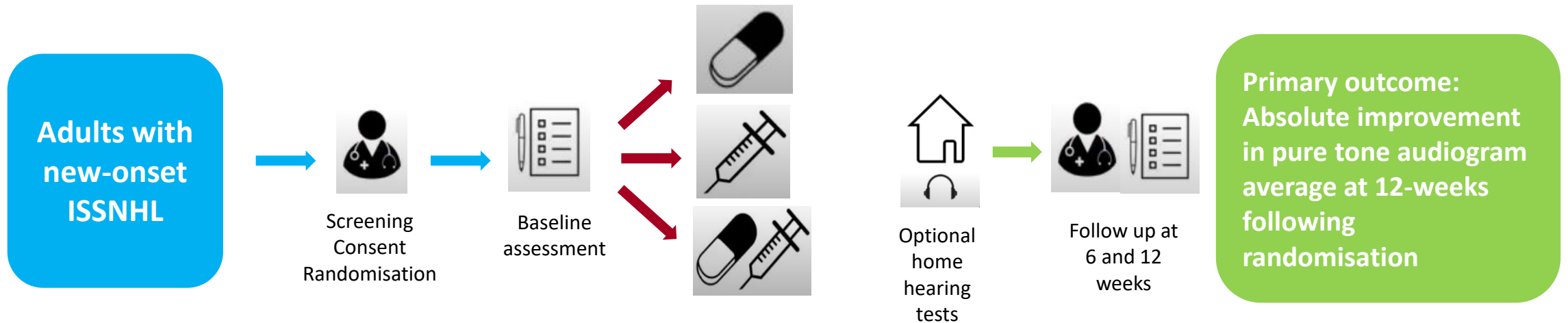
# TRIAL DESIGN



## Population

## Interventions

## Outcomes



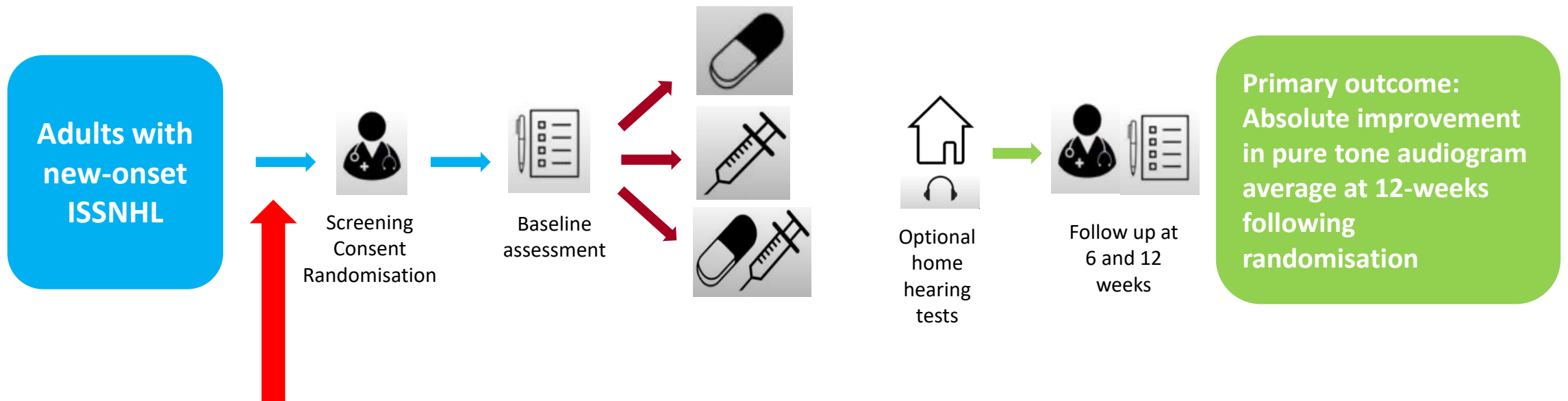
# TRIAL DESIGN



## Population

## Interventions

## Outcomes



**This stage needs everyone to help** - ensuring patients are identified and not unintentionally excluded by treatment

## ELIGIBILITY - INCLUSION



### **Diagnosis of new-onset ISSNHL:**

- Sensorineural hearing loss of 30 decibels (dBHL) or greater
- Occurring within a 3-day period
- Including 3 contiguous pure-tone frequencies (out of 0.5, 1.0, 2.0, 4.0 kHz) confirmed with a pure tone audiogram

Aged 18 years or over

Onset of hearing loss within four weeks prior to randomisation

English spoken as a first or second language

*Exclusion criteria are in Protocol*

**PLEASE IDENTIFY THESE PATIENTS  
AT THE POINT OF REFERRAL**

**The local trial team will then screen  
the patient for suitability**

# PATIENT INFORMATION



- ❖ Potentially eligible participants will be approached by a member of the local STARFISH trial team
- ❖ A **STARFISH Patient Information Sheet** will be given to the patient
- ❖ Patients can be directed to the patient information video on the website: [www.birmingham.ac.uk/STARFISH](http://www.birmingham.ac.uk/STARFISH)





# INTERVENTIONS



Trial participants will be randomised in 1:1:1 ratio to:

**Arm 1**  
**Oral steroid**

OR

**Arm 2**  
**Intratympanic steroid**

OR

**Arm 3**  
**Combined oral and  
intratympanic steroid**

The normal prescribing process and standard pharmacy stock will be used, though must be prescribed by the local trial team.

# INTERVENTIONS



## Oral Steroid:

- ❖ 7 day course
- ❖ Prednisolone 1mg/kg/day (rounded to 5mg) to a maximum dose of 60mg
- ❖ Standard outpatient or FP10 prescription
- ❖ **Participants receive an Oral Steroid Information Sheet**



### Oral Steroid Information Sheet

#### *What are steroid tablets?*

Steroid tablets are commonly used within the NHS to treat many different conditions, including sudden hearing loss.

You have been prescribed a steroid called Prednisolone that is taken in tablet form. You will need to take several 5mg tablets together every day. The dose will be calculated for you and will be written on the box. Steroids are drugs that are similar to a hormone that the body naturally produces, and they act to reduce inflammation.

#### *How should I take my medication?*

Your prednisolone is best taken in the morning after breakfast, at around the same time each day. You should swallow tablets whole with water (do not chew them).

For maximum benefit, it is important that you take the tablets as directed every day, and complete the whole 7 day course of treatment.

Store tablets at room temperature, and out of sight and reach of children.

#### *What if I miss a dose?*

If you miss a dose it can be taken later in the day. If you miss a day, do not worry and do not try and catch up by taking the dose missed from the day before - just take the dose prescribed for that day.

#### *What are the possible side effects?*

Taking prednisolone can be associated with side effects which are mostly mild.

*Less than half of people who take it have:*

- Difficulty getting to sleep
- Mild changes to mood

*Less than 1 in 10 people have:*

- Temporary dizziness
- Indigestion

*Very rare, less than 1 in 10,000 people have:*

- Allergic reaction
- Severe change in mood
- Blood clots
- Bone fracture due to weakness or joint damage


# INTERVENTIONS



## Intratympanic Steroid:

- ❖ 3 injections spaced  $7 \pm 2$  days apart
- ❖ Dexamethasone 3.3 or 3.8mg/ml
- ❖ Standard clinical technique as per online video
- ❖ Local anaesthetic according to local practice
- ❖ If recovery to **near to normal** hearing occurs:
  - Discuss with the patient
  - May omit injections 2 and/or 3
- ❖ **Participants receive an Intratympanic Steroid Information Sheet**

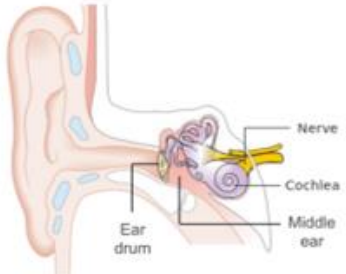
***Please ensure dexamethasone for injection is available out-of-hours***



### Intratympanic Steroid Information Sheet

**What is Intratympanic Steroid Injection?**  
Intratympanic steroid injection is a technique widely used in the NHS already to treat sudden hearing loss and other conditions.

Steroids are drugs that are similar to a hormone that the body naturally produces, and they act to reduce inflammation. Intratympanic injection is a technique to inject steroids through the ear drum. A local anaesthetic is used before the injection, which means that it is usually not painful and patients do not normally have any problems during injection. Steroids are injected through the ear drum and into the middle ear space (see below). From here, they can be taken up into the cochlea, which is the part of the inner ear which senses hearing.



The outer, middle and inner ear (cochlea). The ear drum divides the outer from the inner ear.

**How is the injection performed?**  
A local anaesthetic cream or spray is given to make your ear drum numb so that the injection is not usually painful - this takes between 5 and 30 minutes to work. Using a very thin needle and a microscope to guide it, the steroid is then injected through your ear drum and into your middle ear. You will then remain lying down for 30 minutes after the injection so that the steroid is taken up into your inner ear.

# TIMING OF TREATMENT

## Starting steroid treatment

- ❖ Meta analysis supports limited or no impact of delayed steroid treatment on SSNHL final hearing outcomes (Liebau *et al.* 2017)
- ❖ STARFISH requires patients not to be prior-treated with steroid by primary care, ED or by ENT
- ❖ Participant randomisation and steroid treatment can be delayed until relevant staff or facilities are available e.g. from Saturday to Monday
- ❖ In the combined treatment arm, intratympanic steroid can be delayed and given any time within four days of starting oral steroids

# OUTCOMES – CLINICAL ASSESSMENTS



- ❖ Otoscopy
- ❖ Pure tone audiometry
- ❖ AB phoneme speech audiometry
  - \*There is some flexibility in timing for this outcome; where essential, baseline measurement can be delayed up to 48hrs after treatment
- ❖ ***Recorded at baseline, 6 weeks and 12 weeks***



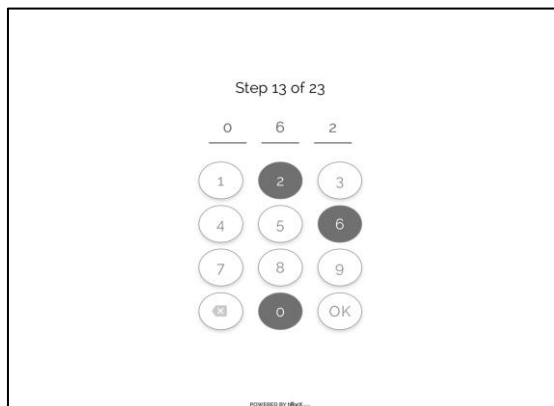
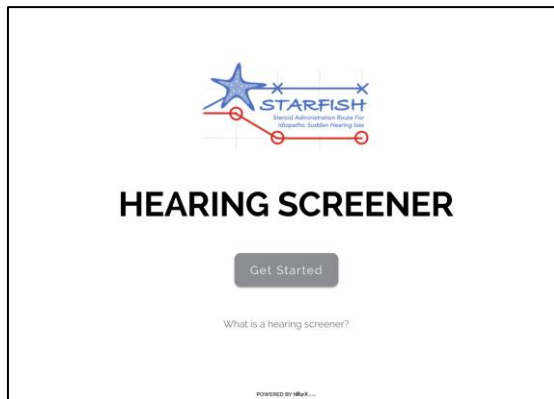
# OUTCOMES – PATIENT BOOKLET

- ❖ Speech, Spatial and Qualities of hearing scale (SSQ)
- ❖ Vestibular Rehab. Benefit Questionnaire (VRBQ)
- ❖ Tinnitus Functional Index (TFI)
- ❖ Health Utilities Index 3 (**HUI3**) and '**ICECAP-A**' questionnaires
- ❖ ***Recorded at baseline, 6 weeks and 12 weeks***

Questionnaire booklet completed on paper, in clinic, checked by local trial team, then returned to the trials unit in pre-paid envelope



# HOME HEARING TESTS



- ❖ Optional home hearing tests for participants
- ❖ To define the trajectory of hearing recovery
- ❖ Strongly supported by our patient group
- ❖ Completed via the trial website every week, for 12 weeks:
  - Digits-in-noise
  - Pure tone audiogram tests (TBC)
- ❖ Consenting participants will be **supplied with earphones**
- ❖ Weekly text message prompts will be sent, including the participant ID

# ASSOCIATE PI SCHEME



## Trainees can choose to be **NIHR Associate PIs**

- ❖ In-work training opportunity
- ❖ A chance to experience what it means to work on and deliver a NIHR portfolio trial
- ❖ 6 month+ involvement required (this can be at more than one site after rotation)
- ❖ Local PI acts as a mentor
- ❖ Online training activities on NIHR Learn
- ❖ Formal certification
- ❖ Recognised by RCS and all colleges

**INTEGRATE**  
The UK ENT Trainee Research Network

**NIHR** | National Institute  
for Health Research



## KEY POINTS FOR A SUCCESSFUL TRIAL SITE

All ENT doctors, audiologists and nurses can help make trial recruitment a success:

- ❖ Ensure potentially eligible participants are passed on to local trial collaborators
- ❖ Do not advise GPs to start steroids prior to hospital review
- ❖ If you can, engage your GP colleagues so they are aware of SSNHL and the need to refer urgently for assessment before starting treatment
- ❖ Engage your audiology colleagues, particularly regarding AB testing
- ❖ Ensure that awareness of the STARFISH trial is included in junior doctor handover: at FY, CT and ST level
- ❖ Use the video training material provided for intratympanic injection and AB speech testing
- ❖ *Get in touch with the central STARFISH trial team if you have any problems*

FIND OUT MORE



INTEGRATE: <https://entintegrate.co.uk/starfish>



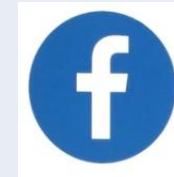
[STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk)



[@STARFISH\\_trial](https://twitter.com/STARFISH_trial)



[www.birmingham.ac.uk/starfish](http://www.birmingham.ac.uk/starfish)



[www.facebook.com/StarfishTrial](https://www.facebook.com/StarfishTrial)