

Title	STARFISH: A randomised controlled trial of STeroid Administration Routes For Idiopathic Sudden sensorineural Hearing loss
Objectives	<p>Primary Objectives:</p> <ul style="list-style-type: none"> To establish the relative effects of oral, intratympanic, or combined oral and intratympanic steroids on hearing recovery in idiopathic sudden sensorineural hearing loss (ISSNHL), when used as first line management. <p>Secondary Objectives:</p> <ul style="list-style-type: none"> To complete a health economic assessment of the different routes of steroid administration. To use participant submitted data to explore the trajectory to hearing recovery. <p>Economic Aims and Objectives</p> <p>To establish the cost-effectiveness of oral, intratympanic or combined oral and intratympanic steroids as the first line of treatment for ISSNHL.</p> <p>Exploratory Objectives</p> <p>To improve the early identification of ISSNHL in primary care.</p>
Trial Design	A pragmatic, multicentre, assessor-blinded, parallel, three-arm intervention, superiority, randomised controlled trial (1:1:1) with an internal pilot.
Participant Population/ Sample Size and Setting	525 participants with sudden hearing loss will be recruited from ~75 NHS hospital Ear, Nose and Throat (ENT) units treating ISSNHL
Eligibility Criteria	<p>Inclusion Criteria</p> <ul style="list-style-type: none"> Adults aged 18 years or over Diagnosis of new-onset ISSNHL- sensorineural hearing loss of 30 decibels (dBHL) or greater occurring within a 3-day period and including 3 contiguous pure-tone frequencies (out of 0.5, 1.0, 2.0, 4.0 kilohertz (kHz)) confirmed with a pure tone audiogram. Onset of hearing loss within four weeks prior to randomisation English spoken as a first or second language <p>Exclusion Criteria</p> <ul style="list-style-type: none"> Identified cause for hearing loss (not idiopathic) e.g. Meniere's Bilateral ISSNHL Received prior steroid treatment for the same episode of ISSNHL Medical contraindication to high dose systemic steroids Previous history of psychosis On oral steroid therapy for another condition Known adrenocortical insufficiency other than exogenous corticosteroid therapy Hypersensitivity to the active substance or to any of the excipients Has a systemic infection unless specific anti-infective therapy is employed Has ocular herpes simplex Has ipsilateral acute or chronic active middle ear disease (including acute otitis media, chronic suppurative otitis media and cholesteatoma, excluding dry perforation) Does not have the capacity to provide written informed consent

Interventions	<ul style="list-style-type: none"> • Oral steroid (Prednisolone) 1mg/Kg/day up to 60mg/day for 7 days; Or • Intratympanic steroid (Dexamethasone) three intratympanic injections 3.3mg/ml or 3.8mg/ml spaced 7±2 days apart; Or • Combined oral (Prednisolone) and intratympanic (Dexamethasone) steroid as described above, with the first intratympanic injection occurring within four days of starting oral steroids. <p>All analysis will have the following two key group comparisons</p> <ul style="list-style-type: none"> ○ intratympanic steroid versus oral steroid ○ combination oral and intratympanic steroids versus oral steroid
Outcome Measures	<p>Primary Outcome</p> <ul style="list-style-type: none"> • The absolute improvement in pure tone audiogram average at 12-weeks following randomisation (calculated at 0.5, 1.0, 2.0 and 4.0 Kilohertz (kHz)) <p>Secondary Outcomes (all at 6 and 12 weeks from randomisation unless stated)</p> <ul style="list-style-type: none"> • Functional hearing: <ul style="list-style-type: none"> ○ Hearing related to speech: using The Speech, Spatial and Qualities of hearing scale (SSQ) ○ Absolute improvement in hearing threshold at six weeks (calculated at 0.5, 1.0, 2.0, 4.0 kHz) ○ Actual hearing thresholds at six and twelve weeks (calculated at 0.5, 1.0, 2.0, 4.0 kHz). ○ High frequency hearing threshold across 4.0, 6.0 and 8.0 kHz ○ Recovery of speech perception: using Arthur Boothroyd (AB) word lists scored by phoneme ○ Extent of hearing recovery: using an established classification of recovery • Associated symptoms: dizziness and tinnitus (Vestibular Rehabilitation Benefit Questionnaire & Tinnitus Functional Index) • Adverse Events <p>Optional</p> <ul style="list-style-type: none"> • Weekly online home hearing tests (speech and pure tone thresholds) <p>Health Economic Assessment</p> <ul style="list-style-type: none"> • Health Utility Index 3 • ICEpop CAPability measure for Adults • Resource usage