Rinri Therapeutics -

Pioneering regenerative cell therapy

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Agenda

- Who are we?
- A cell therapy for hearing loss – Rincell-1
- The Rincell-1 trial
- Integrating the voice of people with lived experience of hearing loss
- Next steps

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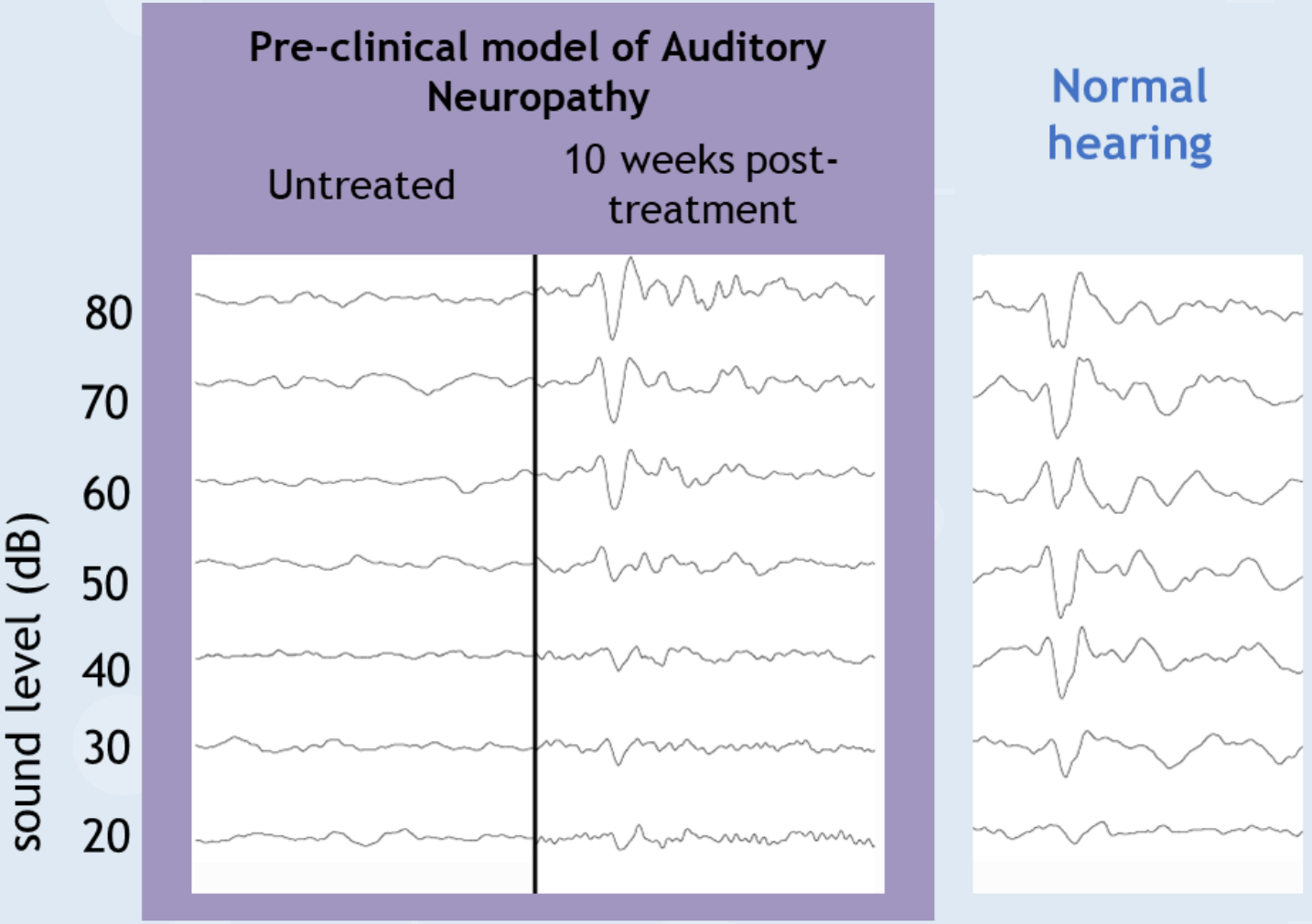
How we started

University of Sheffield



Normal hearing

Chen et al Nature 2012

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Who are we

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University of Sheffield

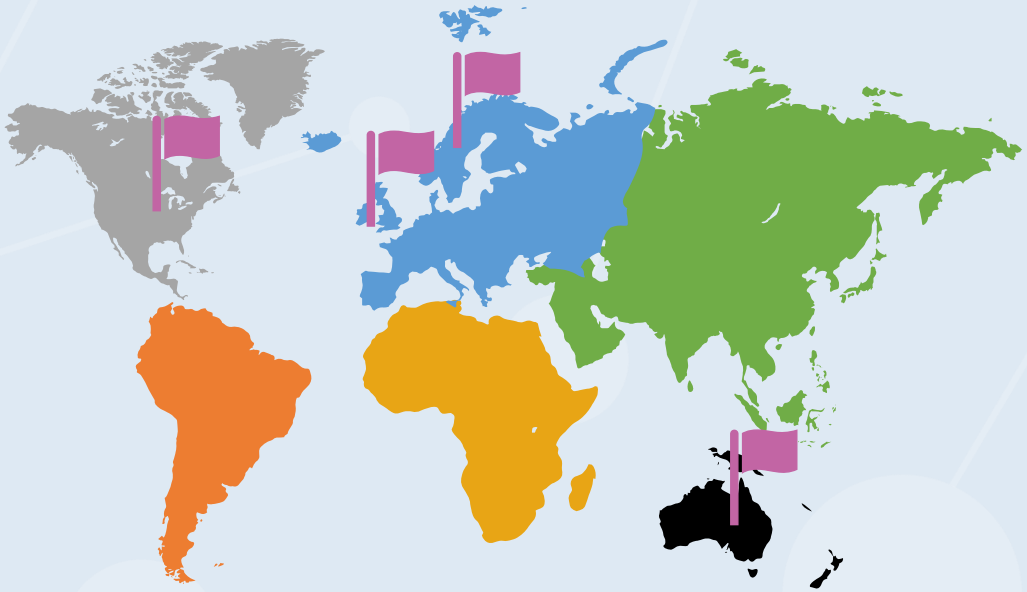
The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Western

NHS
Guy's and St Thomas'
NHS Foundation Trust

UPPSALA UNIVERSITET

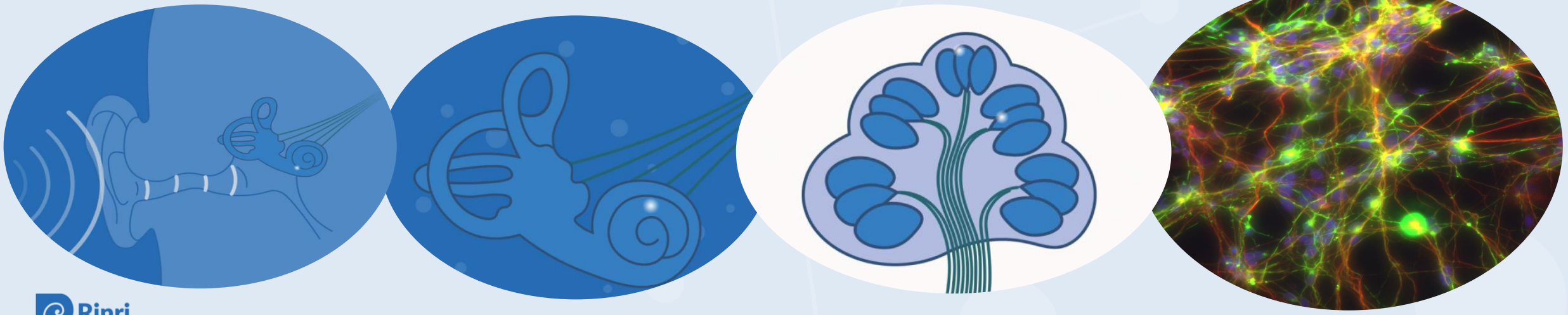
NIHR | Nottingham Biomedical Research Centre



A cell-therapy for hearing loss: Rincell-1

- *Otic Neuron Progenitors* – Specialised cells that are capable of maturing into auditory neurons
- Restores the auditory neurons that connect the inner ear to the brain

Cell therapy uses living cells to replace or regenerate damaged tissues, or to enhance the body's natural ability to heal itself.



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The Rincell-1 trial

First-in-human blinded randomised control trial to assess the safety of Rincell-1 otic neuron progenitor therapy in addition to standard care, compared with standard care alone in severe-to-profound deaf participants with presbycusis, or auditory neuropathy.

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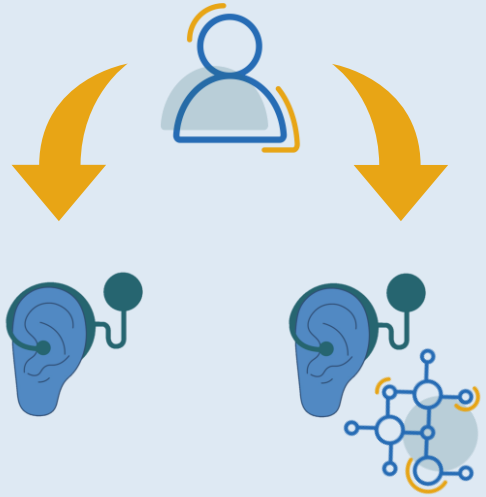
The Rincell-1 Trial

Why?

- Safety
- Effectiveness

How?



Who?

1. Presbycusis (Age-related hearing loss)
2. Auditory Neuropathy

When?

- Rincell-1 + Cochlear implant

- 9 months
- Longer Yearly follow up

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The Rincell-1 Trial

How will we measure success?

1

The cochlear implant has the unique ability to take measurements from the inner ear.

✓Assess inner ear health (e.g. inflammation)

✓Assess number of auditory neurons

2

MRI scans can produce detailed images of brain structure to assess safety

3

Patient-reported outcome measures provide the subjective views of patients on tolerability and effectiveness

+++ Many other clinical tests

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Integrating the patient voice

Research carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them".

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Focus groups

- Deep dive into the experiences of people with lived experience of hearing loss
- Direct feedback to protocol design

Surveys

- Extensive geographical and demographic reach
- Quick answers to research questions

Events/ Social Media

- Direct engagement with members of the public
- Opportunities to learn more and share thoughts

Participant Advisory Group

- Involved throughout the trial
- Direct influence over decision making

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Integrating the patient voice

Next Steps

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Next steps

- Continue working with people with lived experience of hearing loss
- Obtain final Ethical Approval
- Deliver the first-in-human trial
- Explore future applications

“ I would actually be very open to it. Not only for my own benefit. But for future benefits from it and it's something quite exciting.”

CW, CI User

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Thank you!

Questions?

Interested in being involved?

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@RinriTx

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Rinri Website

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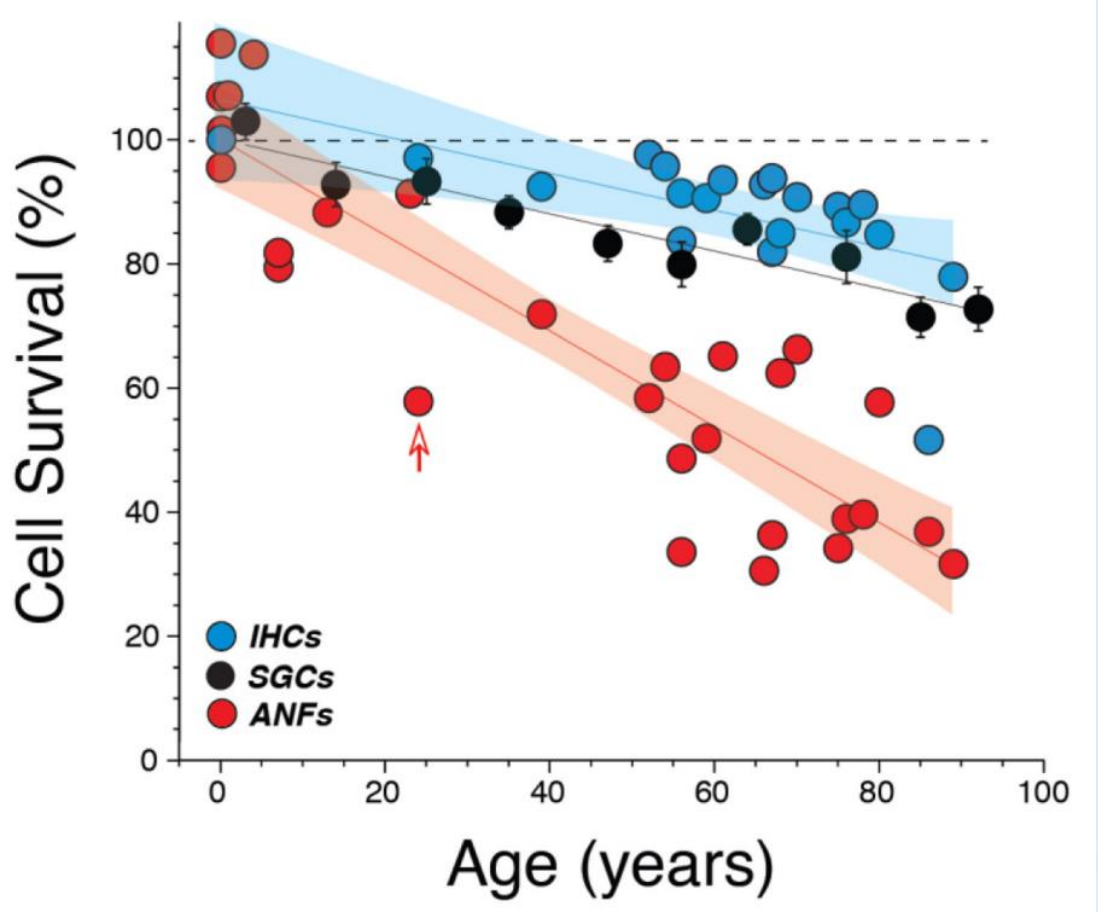
Participants

Adults aged 60 years or over with presbycusis who are eligible for unilateral cochlear implantation as recommended by UK NICE criteria

- 46% loss of auditory neurons at 60 years old, and 69% loss at 90 years old
- >60-year-olds have 60% greater loss of auditory nerve fibers than younger people
- Age-related loss of auditory nerve fibers is 2.6 times steeper than loss of hair cells



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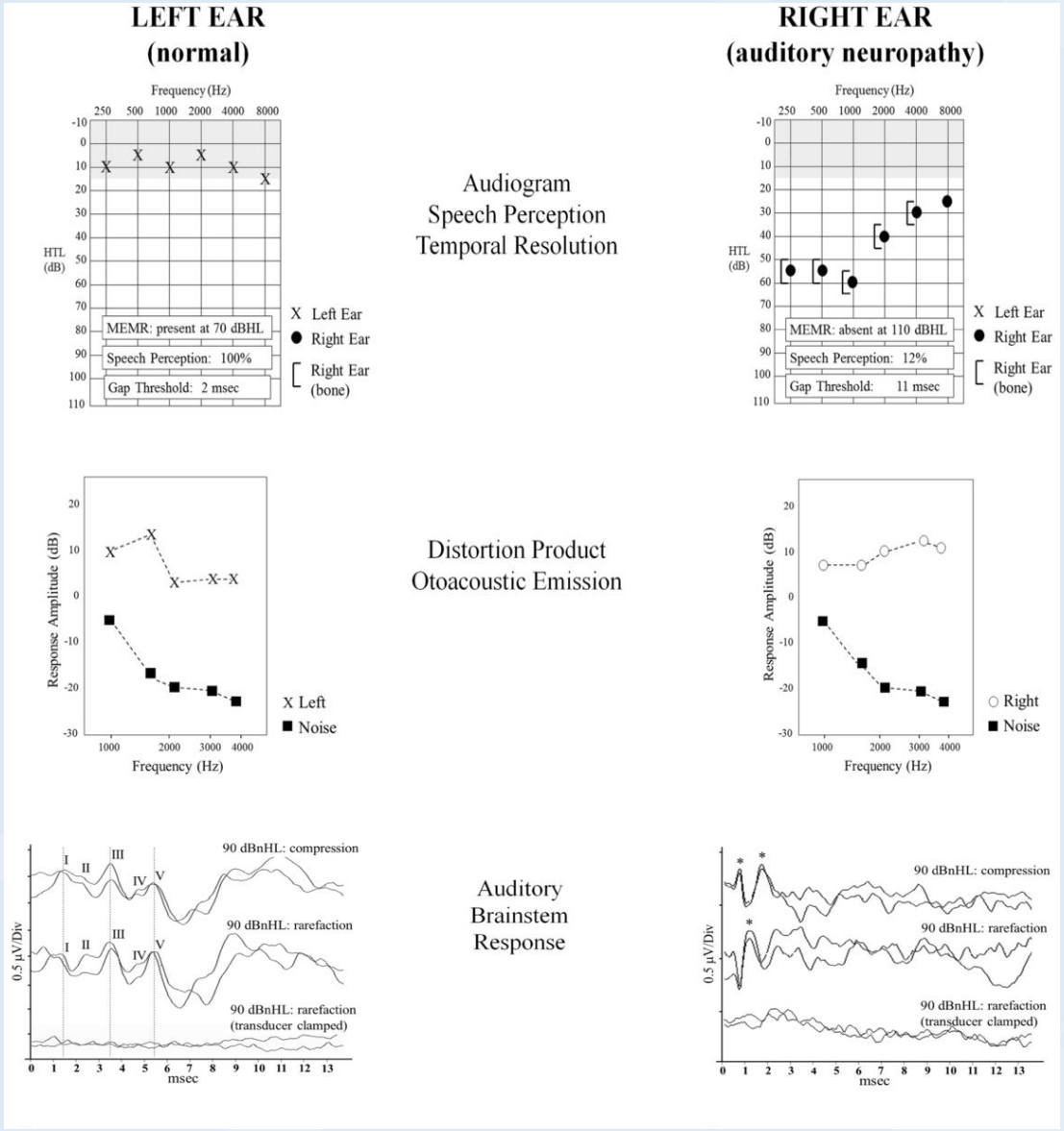
Wu et al 2019

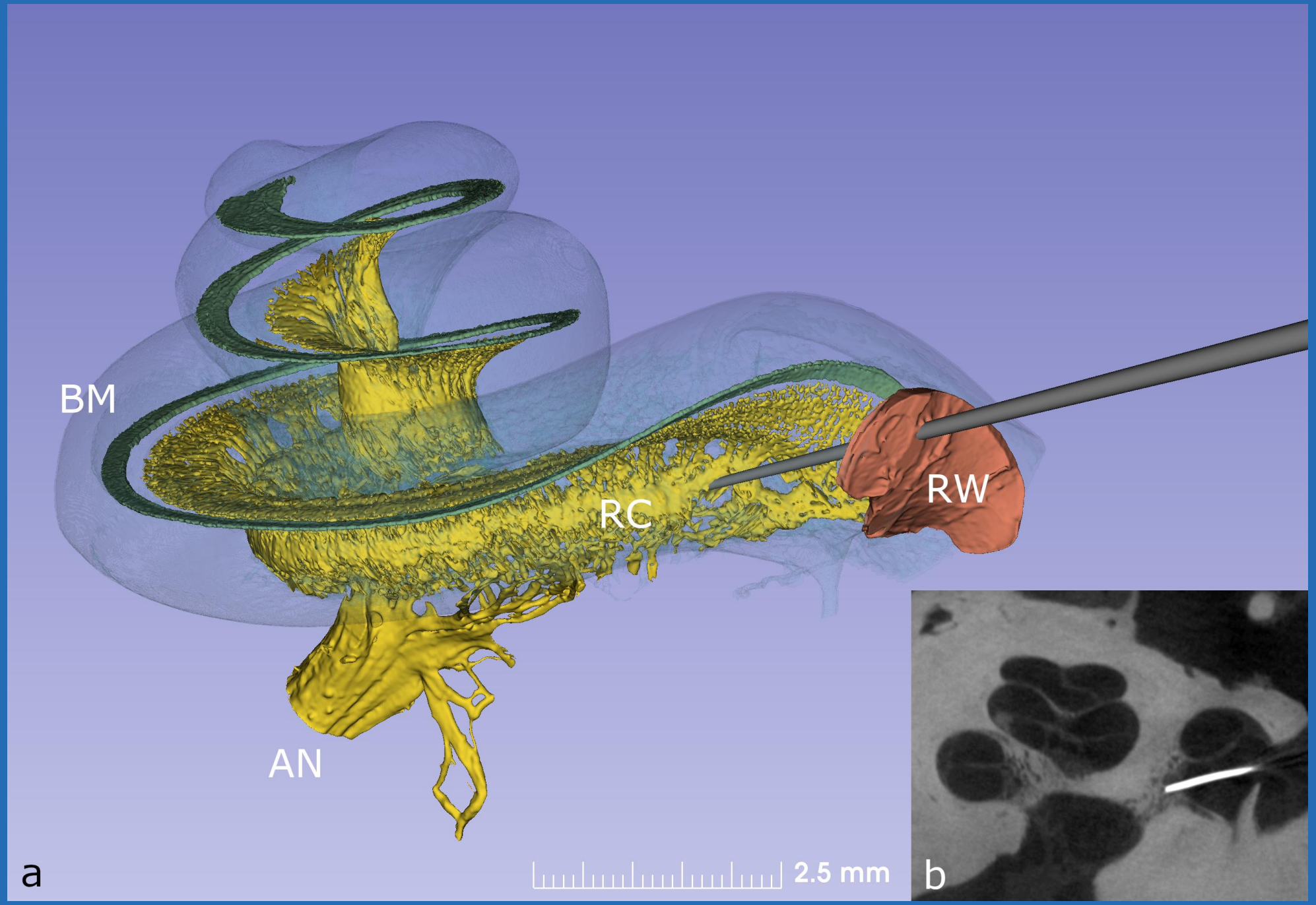
Participants

Adults aged 18 years or older with Auditory Neuropathy who are eligible for unilateral cochlear implantation as recommended by UK NICE criteria

- Less common
- Poor speech perception
- Near-normal pure-tone audiogram
- Normal otoacoustic emissions
- Abnormal or absent Auditory Brainstem Responses

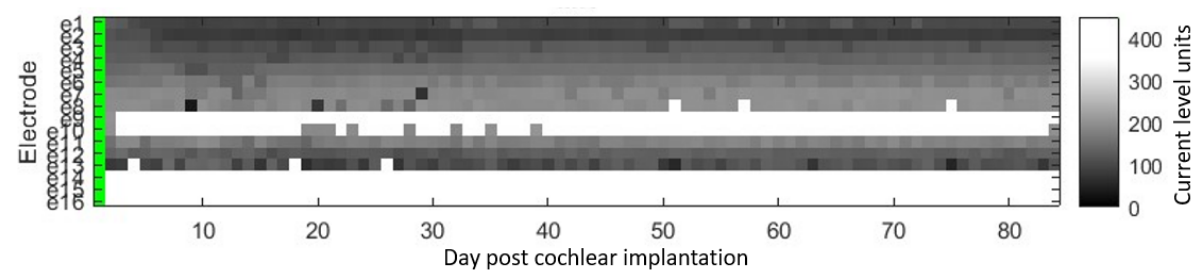


Rance and Starr 2015


BM
RC
RW
AN
a
2.5 mm
b

Objective Measures of Safety and Efficacy

Participants will use their CIs to perform daily measurements of cochlear health to assess safety and efficacy of the treatment.



The feasibility of this approach has been verified in our clinical development work with existing and newly implanted CI users.

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Patient Pathway

Secondary Outcomes

- eCAPs (spiral ganglion cell survival and function)
- eABRs (auditory nerve function)
- PTAs/ECochGs (residual hearing)

Tertiary Outcomes

- Comfort and Threshold levels
- Speech perception testing
- Patient reported quality of life assessments

Timepoints

- 9-month Follow-Up
- Regular Safety Monitoring Visits
- Audiological Assessments: 1, 3, 6, 9 months
- Long Term Follow Up to 10 Years

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