Nonsimultaneous Rapid Pulse Trains (RaPiT) with Current Steering for Loudness Integration as a Basis for a new Loudness Encoding Strategy in Cochlear Implant Subjects

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20838

Source
Nationaal Trial Register

Brief title
RaPiT

Health condition

Hearing Impared

Sponsors and support

Primary sponsor: Prof.dr.ir. J.H.M. Frijns
Source(s) of monetary or material Support: Advanced Bionics Corporation

Intervention

Outcome measures

Primary outcome

To discover the optimal pulse characteristics for controlled loudness growth with rapid pulse trains leading to a single pitch percept and eventually towards understanding of speech.

We will create and evaluate loudness curves for multiple sequentially steered modalities. In the first stage, we will look at pulse characteristics for loudness balancing like pulse amplitudes at threshold level (TL) and most comfortable level (MCL), pulse width, amount of sequential pulses, interpulse interval (IPI) and physical space between stimuli for the different modalities.
In the second stage, we will evaluate loudness growth by matching and ranking the experimental modalities in comparison to monopolar stimulation (MP).

Secondary outcome

Subject characteristics possibly influencing loudness growth or discrimination abilities like electrode position in the cochlea, recent CVC scores, demographics and duration of deafness.

Study description

Background summary

Sequential current steering provides an alternate means of inducing loudness and pitch perception. Frijns et al. (2009) found similar excitation patterns between simultaneous and com-pensated sequential stimulation in a computational model. The comparison of simultaneous and non-simultaneous current steering reveals that a patient cannot perceive differences between a single large pulse and multiple spatially or temporally separated smaller consecutive pulses when the spatial offset and/or temporal delay is small. Presenting pulse trains instead of single biphasic pulses can increase loudness perception without the need to increase the total amount of current per pulse (Van Wieringen et al., 2006). With this principle, it is hypothesized that a pulse train of several small pulses spaced by means of current steering can be perceived as similarly loud as a single larger pulse. Loudness growth will be also greater when a pulse phase is not directly compensated by the opposite-polarity phase, as is the case with conventional biphasic pulses (Deeks et al., 2018). Therefore, we will also create pulse trains where the opposite-polarity phases of the concurrent pulses will follow after all cathodic phases have stimulated the auditory nerve fibers. Unpublished computational modelling work at our clinic has established these pulse trains as a viable option for inducing loudness. Optimal characteristics of these pulse trains in terms of number of sequential pulses, pulse phase duration, interpulse interval and interpulse distance are unknown. This study aims to find the optimal characteristics for pulse trains with sequential current steering for loudness integration in order to induce controllable loudness growth and the perception of a single percept.

Study objective

Nonsimultaneous current steered pulse trains will lead to a single pitch percept whilst reducing the amount of current in comparison to conventional monopolar stimulation

Study design

Three test sessions will be conducted

Intervention

All subjects will undergo loudness balancing and loudness ranking procedures to objectively assess the loudness growth functions. Subjective assessment of sound quality will also be measured.

Contacts

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Eligibility criteria

Inclusion criteria

Adult CI users
Subjects with implantation of CI at least nine months prior to date of measurement
Subjects perform at least 70% at CNC speech test (consonant-noun-consonant) at last clinical measurement

Exclusion criteria

Subjects who are unable to complete a consecutive 3 hours of testing due to medical circumstances or otherwise
Subjects with severe tinnitus
Subjects with hyperacusis

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-09-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8909
Other	METC-LDD : P20.017 / NL72344.058.20

Study results