

The feasibility of Mandibular Advancement Devices for treating Obstructive Sleep Apnoea in patients with quadriplegia.

ACTRN12613000222741

Status RECRUITING
Sponsor David Berlowitz
Enrollment 40 participants

Plain Language Summary

Obstructive Sleep Apnoea (OSA) is a condition where your airway repeatedly blocks during sleep, causing you to stop breathing briefly many times a night. People with quadriplegia (paralysis of all four limbs from a spinal cord injury) are at especially high risk of OSA. Mandibular Advancement Devices (MADs) are custom-made mouthguards that push the jaw forward during sleep to keep the airway open — they are a common treatment for OSA, but their use in people with quadriplegia has not been well studied. This study will check whether MADs are practical and helpful for this group.

You may be eligible if:

- You have traumatic quadriplegia with a spinal cord injury at T1 level or higher
- You are between 18 and 70 years of age

You may NOT be eligible if:

- You have a serious breathing problem called hypercapnic respiratory failure
- You have OSA that needs to be treated immediately
- You have significant dental problems (e.g. gum disease, jaw joint issues, missing teeth)
- You are unlikely to be available for the full study (e.g. planning to transfer out of state)
- You have a condition that would interfere with therapy (e.g. major psychiatric illness)
- You are pregnant
- You have alcohol or drug dependency

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

- Traumatic quadriplegia (T1 or higher lesion)

Exclusion (7)

- Hypercapnic respiratory failure (PaCO₂ >45mmHg)
- OSA necessitating immediate treatment
- Significant dental issues e.g. periodontal disease, TMJ dysfunction, edentulous or insufficient teeth to support the device.
- Likely inability to be followed up until trial completion (eg transfer out of state)
- Condition likely to limit therapy (eg major psychoses, facial or base of skull fractures, etc)

... and 2 more (see full listing online)

Locations (2 total)

Austin Health - Austin Hospital - Heidelberg, NSW,VIC, Australia

Royal North Shore Hospital - St Leonards, NSW,VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12613000222741>

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