PET-B: Post Extraction use of TetraMax Part B (TMB). A comparator controlled clinical investigation comparing the bone healing capability of the investigational product "TetraMax plus BioOss" and the gold standard standard of care comparator "BioOssCollagen" (BioOssCol) for adults who have been treatment planned for tooth extraction/s and implant placement at the same extraction site/s.

ACTRN12619001124123

Status RECRUITING
Sponsor Tetratherix Technology Pty Ltd
Enrollment 43 participants

Plain Language Summary

When a tooth is removed and a dental implant is planned for the same site, the quality of bone healing in the gap is critical for the implant to succeed long-term. This study compares a new bone grafting product called TetraMax combined with BioOss (a well-established bone graft material) against the current gold standard dressing product BioOssCollagen, to see which leads to better bone healing after tooth extraction.

Participants who need one or more teeth extracted and are planning to have implants placed at the same site are randomly assigned to one of the two approaches. The healing of the extraction socket is then monitored over time. This study follows a successful safety run-in phase and is now in its main comparison stage.

You may be eligible if you are 18 or older, have been treatment-planned for tooth extraction and implant placement, and are willing to follow all study visits and requirements. People with active infection at the site, pregnant or breastfeeding women, those on immunosuppressive therapy, those with active cancer, and those taking medications known to affect bone healing (like bisphosphonates) are not eligible.

Key Eligibility Criteria

Inclusion (3)

- •Participants greater or equal to 18 years of age
- •Participants who have been treatment planned for tooth extraction/s and implant placement at the same extraction site/s.
- •Participants willing to give written informed consent and willing to participate in and comply with the investigation requirements.

Exclusion (10)

- •Participants <18 years of age.
- •Participants with acute infection at the target site or a surgical site located near infection.
- •Pregnant or lactating women, or women of childbearing potential who are not willing to avoid becoming pregnant during the study.
- •Participants who are concurrently enrolled in another clinical study, or who have or received an investigational device or drug within the past four (4) weeks.
- •Participants with a history of a psychological illness or condition such as to interfere with the Participant's ability to understand the requirements of the study.

... and 5 more (see full listing online)

Locations (1 total)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12619001124123

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