A Pilot Clinical Study to Evidence Improved Cranial Flap Fixation With a Bioresorbable Bone Adhesive

NCT06780852

Status	RECRUITING
Phase	Not Applicable
Sponsor	RevBio
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (7)

- Subjects or representatives must have voluntarily signed the informed consent form before any study related procedures;
- Subjects can be any gender, but be between (and including) 18 and 75 years of age
- Subject is scheduled for a cranial procedure in the supratentorial location.
- Subject requires a procedure involving a Class I/clean wound (uninfected surgical wound in which no inflammation was encountered).
- Subject, and/or subject's family are able and willing to provide informed consent and HIPAA authorization.

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

Exclusion (11)

- Subject requires a procedure involving a translabyrinthine, transsphenoidal, transoral approach, or any procedure that penetrates the air sinus or mastoid air cells. Note: Superficial penetration of mastoid air cells is not an exclusion if cells were appropriately sealed (e.g., bone wax).
- Subject has clinically significant hydrocephalus or clinical evidence of altered CSF dynamics.
- Subject has undergone a previous, open intracranial neurosurgical procedure in the same anatomical location. (Note: stereotactic biopsy was not exclusionary).
- Subject requires a craniectomy (the bone flap is not replaced during the current surgery).
- Subject had radiation treatment to the surgical site, or standard fractionated radiation therapy was planned post index-procedure. (Note: stereotactic radiosurgery prior to the planned index procedure was not an exclusion criterion.)

... and 6 more (see full listing online)

Locations (1 total)

Bristol Southmead Hospital, Bristol, United Kingdom