The ROSEND Trial - A Randomised trial for the treatment of recalcitrant symptomatic rosacea using definitive volumetric modulated arc radiotherapy or standard dermatological treatment

ACTRN12622001585718

Status	RECRUITING
Phase	Phase 2
Sponsor	Icon Cancer Foundation
Enrollment	40 participants

Plain Language Summary

Rosacea is a chronic skin condition that causes redness, flushing, and visible blood vessels, mainly on the face. For most people it can be managed with creams and antibiotics, but for some it keeps coming back despite treatment — causing significant distress and affecting quality of life. This group of patients with stubborn, recurring rosacea is the focus of this study.

The ROSEND trial is comparing standard dermatological treatment (topical creams, antibiotics, or laser) against a specialised form of radiotherapy called volumetric modulated arc radiotherapy (VMAT). Radiotherapy is already used to treat certain skin conditions, and researchers believe it may be able to provide longer-lasting control of rosacea by targeting the underlying biology of the condition.

You may be eligible if you are aged 50 or older, have had rosacea for at least 10 years, have relapsed after at least one systemic and one topical treatment, and have a moderate to severe rosacea severity score. People with previous radiation treatment to the same area, a radiation sensitivity disorder, HIV infection, or where telangiectasia (visible blood vessels) is the primary feature are not eligible.

Key Eligibility Criteria

Inclusion (8)

- years of age or over.
- Recalcitrant and relapsing rosacea, defined as those who have suffered with rosacea for at least 10 years and have relapsed following treatment with at least one standard systemic therapy and one standard topical therapy. Prior therapy must have been administered for at least 12 weeks.
- Rosacea score of 3-4 as defined by the IGA scale for rosacea.
- Able to have punch biopsies as described for the translational component of the study.
- Able to receive VMAT RT to 36 Gy in 20 fractions within 8weeks for this condition.

... and 3 more (see full listing online)

Exclusion (5)

- Rosacea where Telangiectasia is the primary feature.
- History of a radiation sensitivity syndrome.
- Previous in-field RT.
- Previous in-field invasive skin cancer treated within 4 weeks of enrolment.
- Human Immunodeficiency Virus infection.

Locations (3 total)

Icon Cancer Centre Revesby - Revesby, NSW, Australia
Icon Cancer Centre Gosford - Gosford, NSW, Australia
Icon Cancer Centre Wahroonga - Wahroonga, NSW, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622001585718