GENTLER TRIAL SYNOPSIS

Data category	Information
Scientific title	The GENTLER Trial: **G**enesisCare **E**pithelial **N**eoplasia **T**rial using **L**ighter dose **E**xtensive field **R**adiotherapy
Trial registry	ACTRN12620000618954p
Intervention(s)	Wide-field volumetric modulated arc therapy (VMAT) radiotherapy for the skin, planned according to a GenesisCare national protocol but with a dose reduction to a total of 30 Gy in 15 fractions.
Study Design	Open-label, non-randomised, phase II pilot study of low-dose wide-fiel VMAT radiotherapy for the skin; 100 patients

Key Inclusion Criteria:

- Aged 50 years or greater
- Have symptomatic extensive skin field cancerisation (ESFC) greater than 50 cm^2.
- Has been reviewed and referred by a Dermatologist and/or medical professional with expertise in dermatoscopy prior to treatment to exclude the presence of invasive cancer in the treatment field.
- Fulfil at least two of the following three criteria:
  - Karnofsky performance score of ≤ 70
  - Unable to complete a fully fractionated, long-course of treatment due to a comorbidity or the requirement for nursing home care.
  - Aged ≥ 70 years
- Declined or deemed unsuitable for other local therapies (i.e. excision, topical, cryotherapy)
- Charlson Comorbidity Score ≥5
- Willing to use adequate contraception measures (both in vivo and in vitro) during and for six months after radiation treatment for participants who will engage in the conception of a child

Key Exclusion Criteria:

- Received local therapy within the last 4 weeks. This includes excision, cryotherapy, photo-dynamic therapy, radiotherapy or topical agents
- Have a clinically or biopsy-proven invasive skin malignancy within the treatment field to be treated which has either been untreated, or incompletely excised within the last 6 months.
- Currently receiving systemic chemotherapy or treatment with new targeted drugs
- Are concurrently using radio sensitising drugs for medical comorbidities
- For patients who are having lower limbs treated and have any of the following:
  - Chronic lymphoedema with pitting oedema, peripheral vascular disease in the form of intermittent claudication or critical ischemia
  - Chronic leg ulcer within the proposed treatment field.
  - Relapsing cellulitis
- Have received prior radiotherapy to the same treatment site.

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