Liverpool Cancer Trials Unit

TITAN:

CANCER RESEARCH UK

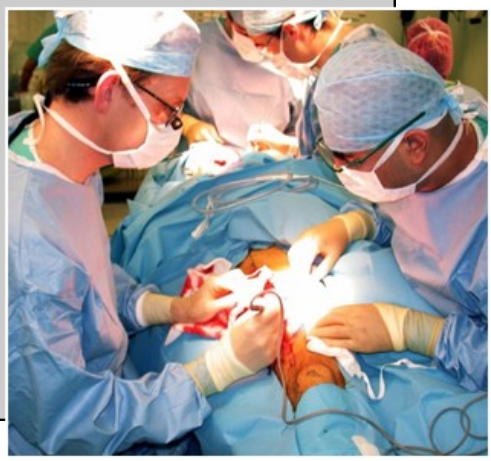
Trial of Induction TPF Therapy in Advanced Head & Neck Cancer.

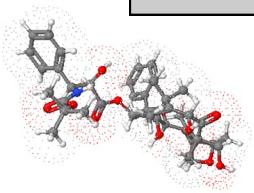
BACKGROUND:

TITAN is a open-label randomized controlled trial conducted in patients with previously untreated locally advanced head and neck squamous cell carcinoma

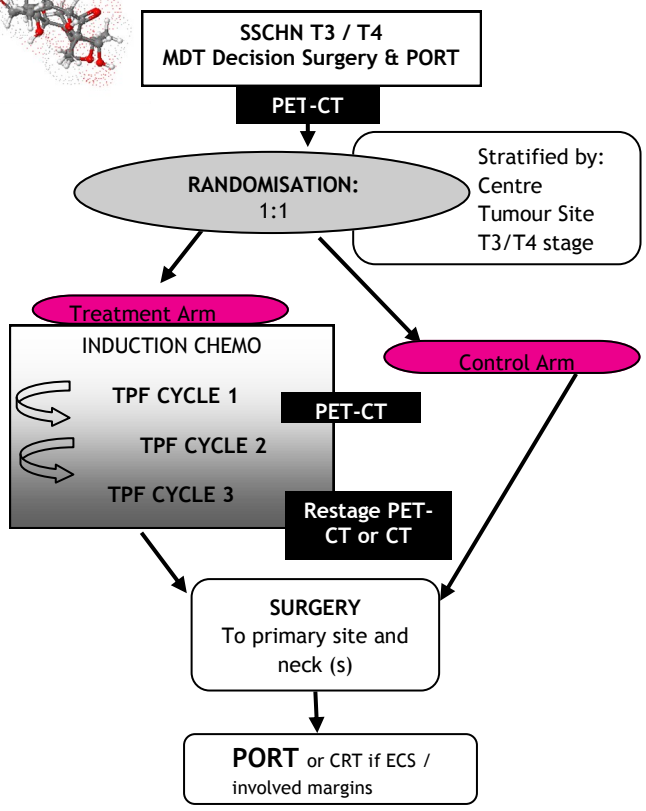
Induction chemotherapy (Docetaxel, Cisplatin and 5-FU) is a significant recent advance in the management of locally advanced SCCHN, although its use in combination with surgery and postoperative radiotherapy (PORT) is under-researched

TITAN address the potential survival advantage of TPF induction chemotherapy prior to surgery and radiotherapy for locally advanced resectable SCCHN.





TRIAL DESIGN



INCLUSION CRITERIA

1. Age ≥18 years
2. Histopathological diagnosis of head and neck squamous cell carcinoma
3. T stage in one of the following site categories:
   a. Lip/ Oral cavity: stage T3 or T4a (and >=4cm in largest dimension)
   b. Paranasal /nasal: stage T4a
   c. Larynx: stage T4a
   d. Hypopharynx: stage T3 or T4a
   e. Cervical oesophagus: stage T3 or T4a
   f. Oropharynx: stage T3 or T4a and HPV-ve
4. Any N stage
5. M0
6. In MDT decision to offer surgery as primary modality of treatment
7. WHO performance status 0 or 1
8. Resectable by conventional criteria in both primary site and any cervical lymph node involvement

STATISTICAL CONSIDERATIONS

TITAN Feasibility Study:

The **primary outcome** is recruitment over a 12 month period from at least 4 centres.

The **secondary outcome** measures are:

1. Randomisation: Screening Ratio
2. The percentage of patients in the TPF arm who complete the full course of treatment (including PORT / CRT)

FOR MORE INFORMATION:

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