FONDAZIONE POLICLINICO UNIVERSITARIO AGOSTINO GEMELLI

UNIVERSITA' CATTOLICA DEL SACRO CUORE

RADIOTERAPIA ONCOLOGICA – GEMELLI ART

ULISSE: Umbrella protocoL ISSue for oncological patiEnts

Clinical Trial

AIM OF THE STUDY

The primary and general objective of ULISSE for oncological patients is to facilitate the development and validation of multi-factorial prediction models for different treatment outcomes. The long term aim is to build a Decision Support System (DSS) based on validated prediction models in order to personalise treatments in terms of both treatment efficacy and toxicity control. The DSS also has the objective of identifying patients for inclusion in future randomised clinical studies stratifying the different risk classes depending on the outcomes identified each time.

BACKGROUND

Our general hypothesis is that we will improve the performance of prediction models for survival and toxicity, if we develop multifactorial models. The basic models will be based on patient related variables (e.g. age, sex), clinical presentations of the disease (e.g. staging, markers, imaging data), treatment data (e.g. chemotherapy, radiotherapy, surgery information, palliative care) and imaging data (diagnostic, treatment or follow-up images). The improved multifactorial models will include additional clinical and treatment imaging and/or genetic information even though no biological data will be actively collected in this project.

STUDY DESIGN

This is a retrospective and prospective study. The study involves the identification of tumour variables and definition of measurement units. Each variable has to be included in a terminological system, an ontology, organised in three tiers:

- Registry Level: the first and most general level that includes the minimal information used for epidemiological analysis only.
- Procedure Level: the intermediate tier that collects data related to treatment and toxicities developed.
- Research Level: the most detailed tier that collects clinical and imaging data to develop an advanced research programme.

Data collection will allow for predictive model creation for survival and related toxicity treatment. The same data could be used to compare the outcome of new treatment options both in Radiation Oncology and Clinical Oncology (target therapies/chemotherapy schedule) with standard care.

AIMS

Primary Aims:
1. To develop, validate and improve predictive models for overall survival, local control, disease free survival and metastasis free survival.
2. To develop, validate and improve predictive models of the onset of acute and late toxicity related radiotherapy treatment.

Secondary Aims:
1. To use predictive models to better inform patients regarding treatment risks (acute and late toxicity) and benefits (overall survival).
2. To use predictive models to identify the best treatment for each patent.

3. To use predictive models to find the potential benefit of new radiotherapy techniques or new care models.
4. To compare new therapeutic options, introduced in clinical practice, with standard care, in terms of radiotherapy toxicity, symptoms referred, quality of life and overall survival.

INCLUSION CRITERIA

All patients arriving at participating Centres for cancer treatment will be eligible for the trail.

- For retrospective data, the information will be collected in a local electronic databank. Data will be rendered anonymous in the local centre and only shared for research aims.
- For prospective data, patients enrolled will be informed of the trail by doctors during their first examination. An informed consent will be signed and stored.

TREATMENT SCHEDULE

Patients will receive treatment as an internal schedule or clinical standards course.