The RADAS study

Does addition of post-operative radiotherapy improve PFS for patients with residual cancer after NACT and surgery?

Study Population

Patients with epithelial ovarian cancer in Stage III and IV, who have had NACT before surgery.

Inclusion Criteria:

Patients who have residual tumor after NACT and surgery

Performance status: 0 or 1

Exclusion Criteria:

Patients with no residual tumor after NACT

Non-epithelial cancers

Inoperable patients

Prior abdominal radiotherapy

Disseminated peritoneal disease

Patients with cancer in organs that cannot be radiated

Study Design:

Randomized study with

Phase I

10-20 patients

Phase II

50-100 patients

Phase III

180 patients in the study arm

90 patients in the control arm

Primary endpoint:

PFS

Secondary endpoints

OS

Quality of life

Methodology

Patients in the study arm will have clip/clips placed during surgery where the ensuing radiotherapy has to be applied. Patient consent needed beforehand.

Radiotherapy can be done by either

- Proton radiotherapy
- Stereotactic body radiotherapy or
- Stereotactic ablation radiotherapy

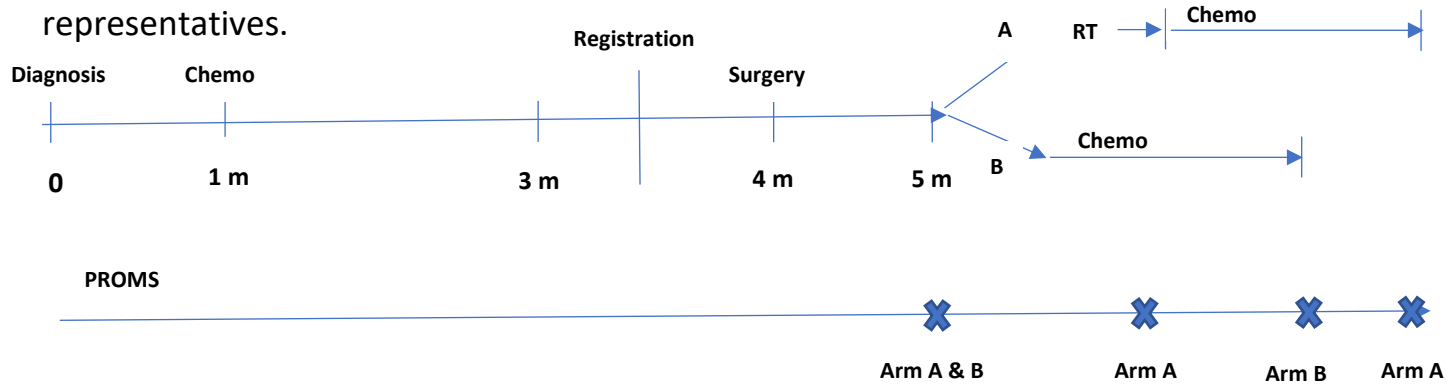
Stratification

By

Quality of Life

Measured by EORTC QLQ-C30 and EORTC QLQ 28

PROM to be developed by the investigator and his team and two patient representatives.



Study Team

Prime investigators: radiologist and gynaeoncologists
medical oncologist, pathologist, statistician, anesthetist and psych oncologist

Study Sites

ESGO ENGOT members.
Surgeons certified by ESGO

Duration of the study

Literature research

3-12 months

Phase I 3 – 5 years

Phase II 5 years

Phase III 5 years

Publication: 2 more years