

HYPROSAR Protocol outline

Pre treatment evaluation at time of Initial presentation

- Routine investigations – Heamogram, Clinical biochemistry, X ray Chest, Plain radiograph of the local site as indicated
- MRI for the loco-regional part, PET-CT (Optional) ; CECT Chest (Mandatory)
- Biopsy (CT guided core biopsy preferred): HE stain, IHC & Molecular genetic profile
- Pathological classification as per WHO Classification (2002); Staging as per AJCC/UICC (2010)

Review by the Joint Sarcoma Tumour Board

Primary Inoperable STS
or patient refusal or medically unfit for surgery

Recurrent Inoperable STS
or patient refusal or medically unfit for re-surgery

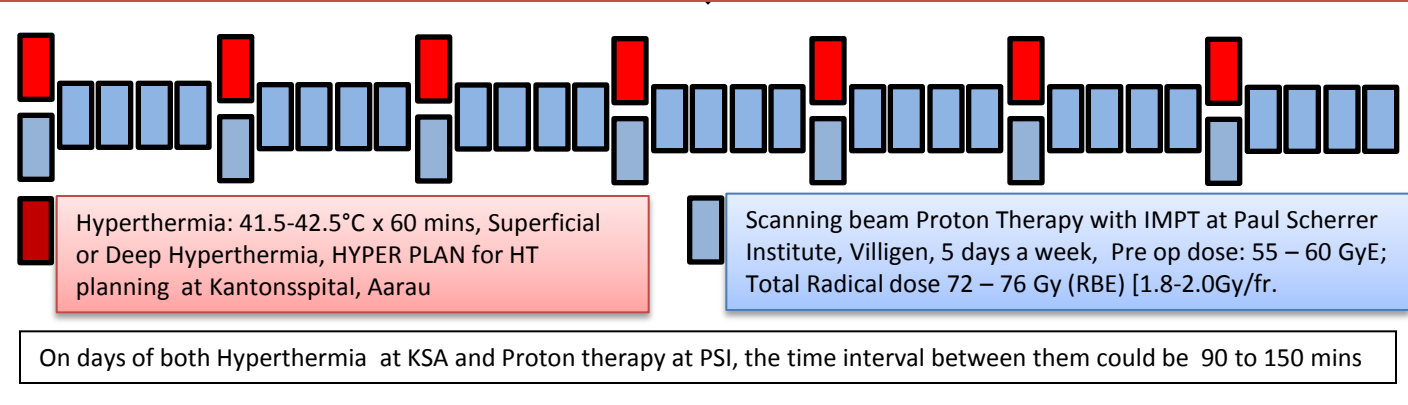
Criteria for Inoperability to be defined and decided by Surgeon on case by case basis

Key Inclusion Criteria

- Histopathologically proven STS
- Stages T2 and T3, G2 or 3, M0 (Stages IIB and III).
- Tumours <5cm could be included if unresectable
- Age ≥ 18 years, ECOG 0, 1
- Ability to comply with the protocol & agree to submit informed consent
- Primary and Unresectable STS at diagnosis, Recurrent STS
- No prior radiotherapy at the site of proposed treatment

Key Exclusion Criteria

- RMS, Extraosseous Ewings, PNET, Desmoids, GIST, Dermatofibrosarcoma protuberans, Osteosarcoma, Chondrosarcoma, Kaposi's sarcoma, Angiosarcoma
- Prior RT at site of treatment
- Intraabdominal STS
- Use of NACT before RT or Surgery
- N+ or M1
- Metal implants, pacemakers, clustered markers



Once weekly monitoring & evaluation each at KSA and PSI during the course of therapy: Local response, acute radiation morbidities, any added morbidities due to hyperthermia, heamatology, biochemistry (as and when indicated)

Trial Stoppage Criteria: If 2 of first 3 patients have grade IV or 5 out of first 8 patients have grade III/IV acute morbidity attributable to treatment

1st follow up: 4 weeks post treatment
Response assessment: Clinical and Radiological

Review by Sarcoma Tumour Board

Good response: May be considered for Surgery and attempt for R0 resection

To evaluate resected specimen for pathological response & molecular genetic studies

Follow up and close monitoring for response and toxicities

If still considered inoperable: Patient to be kept on follow-up, review till 3 months, if good response may consider for surgery