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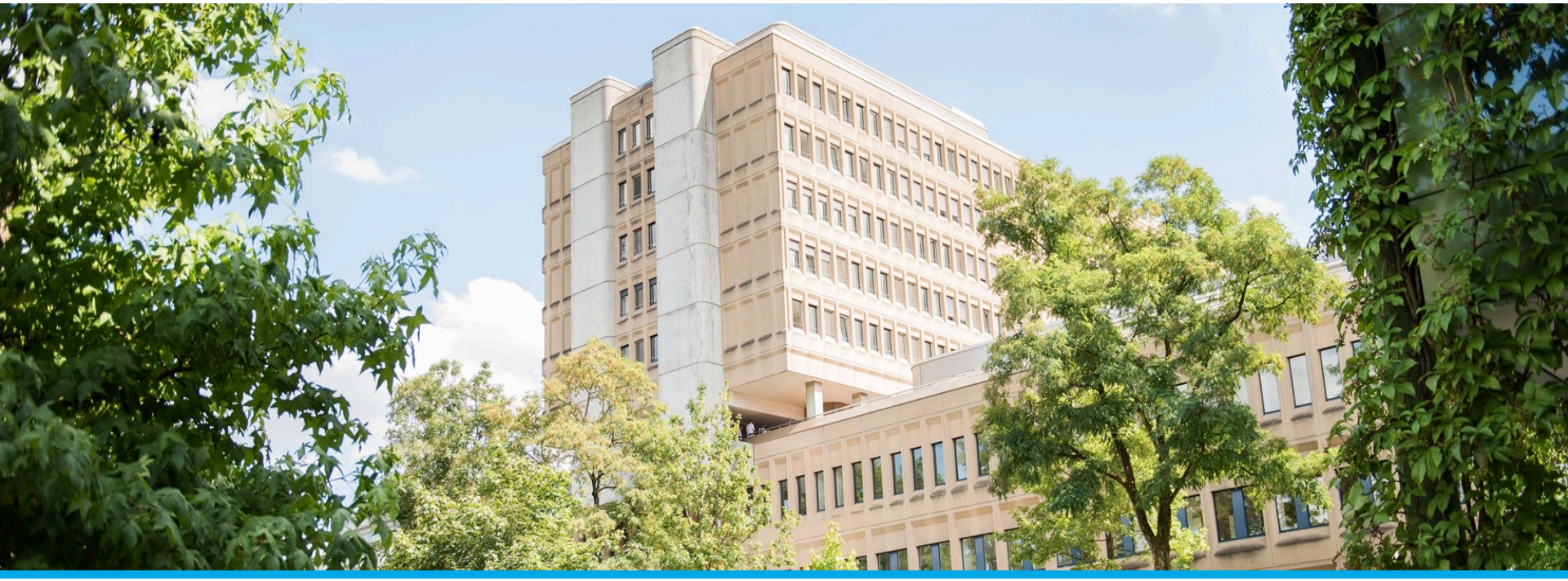
PREOP-2: a randomised phase II trial of **preop**erative versus postoperative radiosurgery for brain metastases indicated for resection



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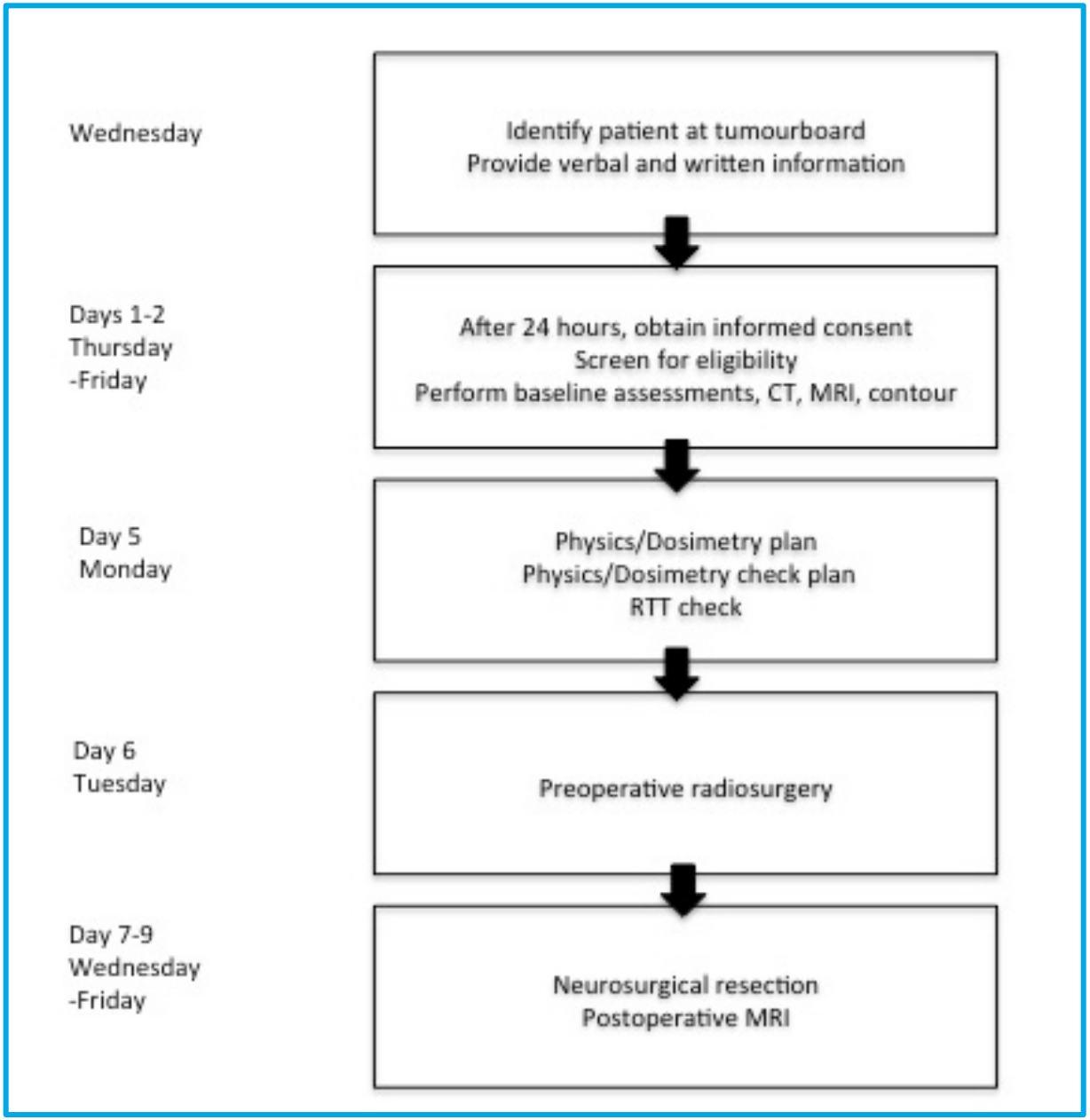
Preop-1: single arm phase II, pilot data

- 10-20 KSA patients (until Preop-2 opens)
  - Age ≥18, KPS ≥70
  - Histological diagnosis of primary or metastatic cancer
  - Ability to take steroids
  - MRI-diagnosis of a clearly demarcated contrast-enhancing brain metastasis up to 5 cm diameter indicated for neurosurgical resection (tumorboard decision). Up to 3 other brain metastases (max. 7cm^3 total volume) for primary radiosurgery/stereotactic radiotherapy.
  - Survival estimated by primary clinician >6 months
- Primary endpoint: incidence of leptomeningeal disease at 12 months
- Secondary endpoint: local control, overall survival, neurological death, quality of life (EORTC QLQ C-30 and BN-20)
- Exploratory endpoints: time to SRS, time to neurosurgery, correlative pathology study


Wednesday
Identify patient at tumourboard
Provide verbal and written information
Days 1-2
Thursday
-Friday
After 24 hours, obtain informed consent
Screen for eligibility
Perform baseline assessments, CT, MRI, contour
Day 5
Monday
Physics/Dosimetry plan
Physics/Dosimetry check plan
RTT check
Day 6
Tuesday
Preoperative radiosurgery
Day 7-9
Wednesday
-Friday
Neurosurgical resection
Postoperative MRI

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Preop-2: Randomised phase II trial, multicentre

- Hypothesis: Reduction in the incidence of leptomeningeal disease from 16% with postop hypofractionated stereotactic radiotherapy

  (5 x 6 Gy to 70-80%, 2mm PTV margin, consensus guidelines *Soliman et al*)

  to 4% with single fraction preop SRS at 12 months *Patel KR et al 2017 J Neurooncl*

  (1 x 15-18 Gy, 1mm PTV margin)

- n=200 (160 + 20% drop-out due to death from extra-cranial disease)
- Multicentre trial, centres with both neurosurgery and stereotactic RT
- Same endpoints
- Grant application decision due 01.04.2020
- International research partners welcome. Feasibility survey to follow.

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