

# Hypofractionated RT in Cervix Cancer

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# Hypofractionated RT in Cervix Cancer:

*Clinicaltrials.gov*

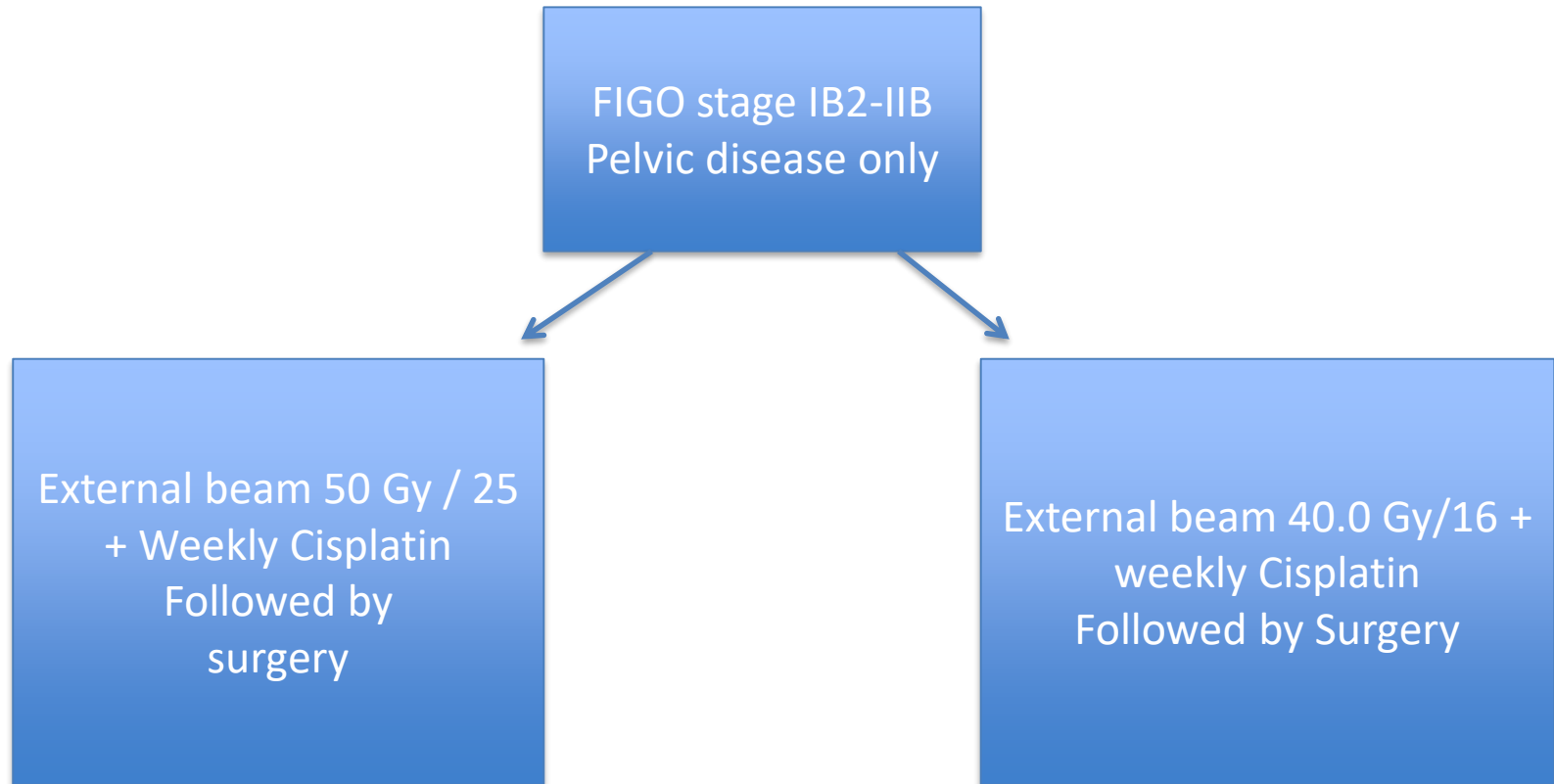
- 919 cervix trials
- 134 hypofractionated RT trials
  - Prostate, breast, NSCLC, GBM
- 0 cervix trials with hypofractionation



# Definitive Treatment: Hypofractionation EBRT

- 45-50.4 Gy, Is this optimal?
- Dose per fraction: 1.8-2.0 Gy?
- Guiding principle: Mitigating late toxicity

# Definitive Trial: Phase II - No brachytherapy



# Definitive Trial: No brachytherapy

- Surgery:
  - Radical hysterectomy 4 -6 weeks after radiation with removal of only abnormal nodes at that surgery and sampling of pelvic and para-aortics
  - If positive para-aortics – treatment with radiation therapy
  - No surgery – if progression of disease

# Definitive Trial: No brachytherapy

- Chemotherapy:
  - Weekly cisplatin – will give 5 courses in both arms
- Endpoints:
  - Primary: PRO –EORTC and Cervix Subscale from FACT
  - Secondary: relapse free survival, overall survival, complications: including days in hospital after surgery and blood transfusion, pathological response

# Definitive Trial: No brachytherapy

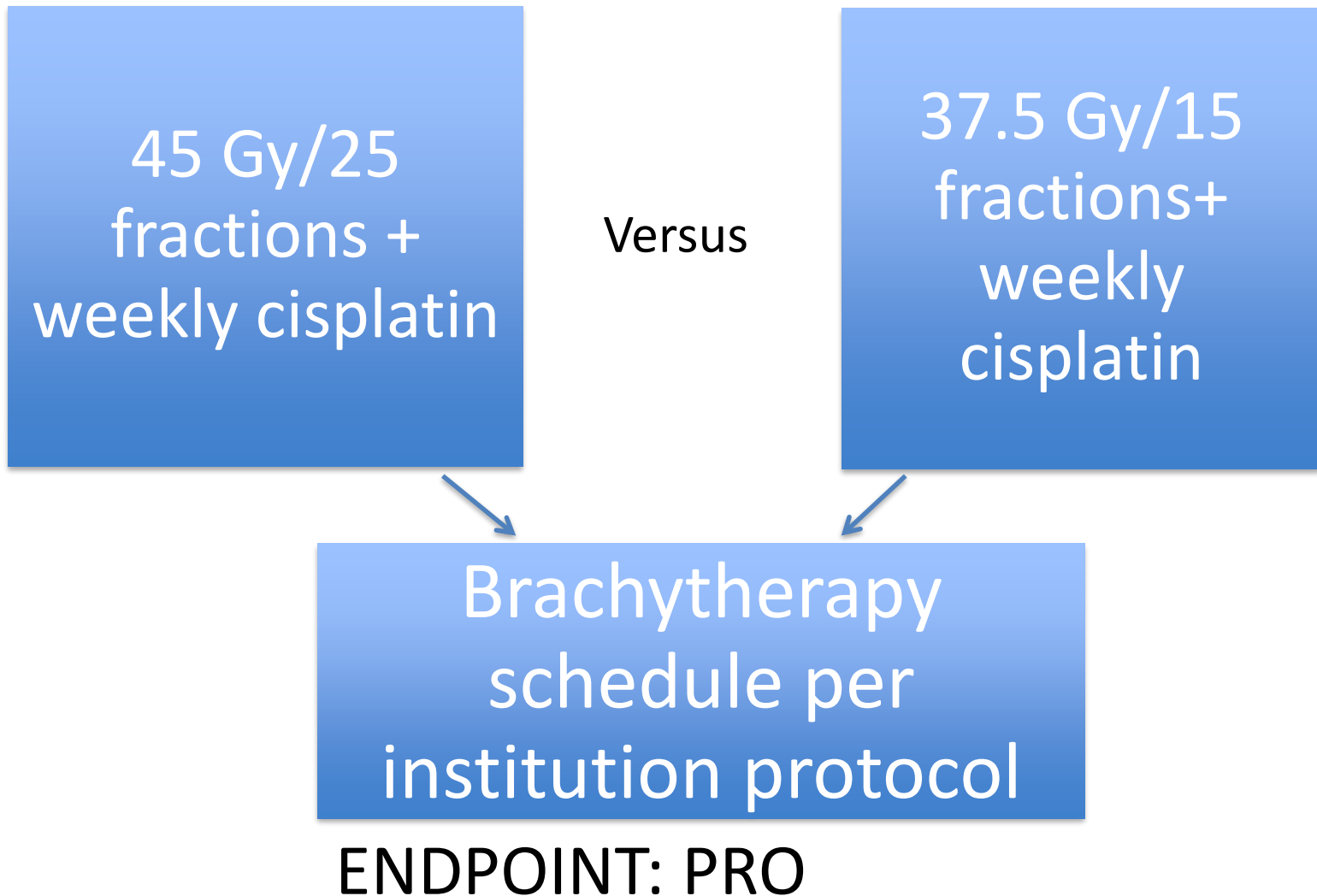
Time Point	Purpose
Before RT	Baseline
2 weeks after RT start	Compare early acute toxicity
End of RT/chemotherapy (at 5 weeks in both arm)	Maximum difference in acute toxicity
4-6 Weeks after RT (before surgery)	Compare resolution of acute toxicity
6 months after RT	Compare toxicity after surgery
1 year from the start of RT	Early chronic toxicity
2 years from the start of RT	Long term toxicity

# Definitive Trial: No brachytherapy

- Early stopping rules – after 10 enrolled patients/per center and then every 20 enrolled patients
- If increase toxicity seen – then terminate trial



# Definitive CRT: Phase II Randomize



# Definitive Trial: brachytherapy

- Chemotherapy: weekly cisplatin?
- Endpoints:
  - Primary: PRO – Expanded prostate cancer index composite (EPIC) and Cervix Subscale from FACT
  - Secondary: relapse free survival and overall survival and chronic complications