

# EAU23

## MILAN, ITALY

10-13 March 2023

Cutting-edge Science at  
Europe's largest Urology Congress

Imperial College  
London



### A0519 Novel trial designs in localised prostate cancer: Pilot phase results from the Prostate Pathway Embodied Comparative Trial (IP3-PROSPECT)

Bass EJ, Fiorentino F, Szigeti M, Klimowska-Nassar N, Sasikaran T, Jadav P, Rawlins F, Oblak M, Khoubehi B, Winkler M, Nasser M, Pope A, Sokhi H, Dudderidge T, Arumainayagam N, Sydes MR, Ahmed HU

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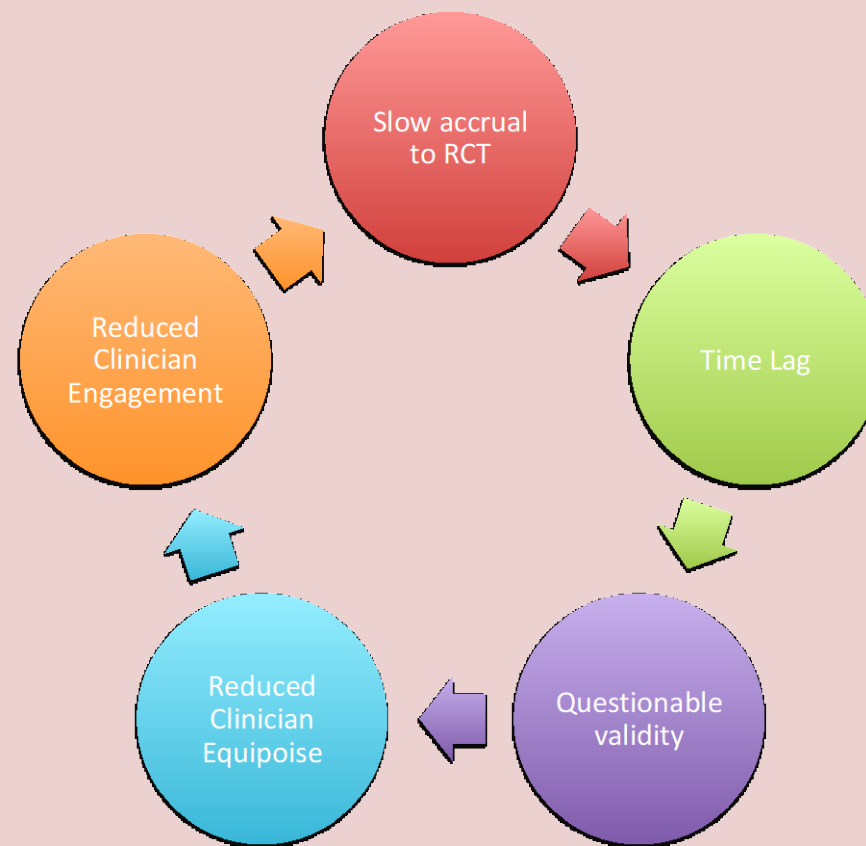
## Conflict of Interest Disclosure

**I have the following potential conflict(s) of interest to report:**

In the last 3 years, HUA has received core research funding from the Wellcome Trust, Medical Research Council (UK), Cancer Research UK, Prostate Cancer UK, The Urology Foundation, BMA Foundation, Imperial Health Charity, NIHR Imperial BRC, Sonablate Corp.

In the last 3 years, HUA has received consultancy honoraria from Sonablate Corp, Boston Scientific and Francis Medical.


- Level one evidence usually obtained from double-blinded RCTs.
- Completing RCTs investigating localised prostate cancer interventions is challenging
- Identified need to determine if other designs work.




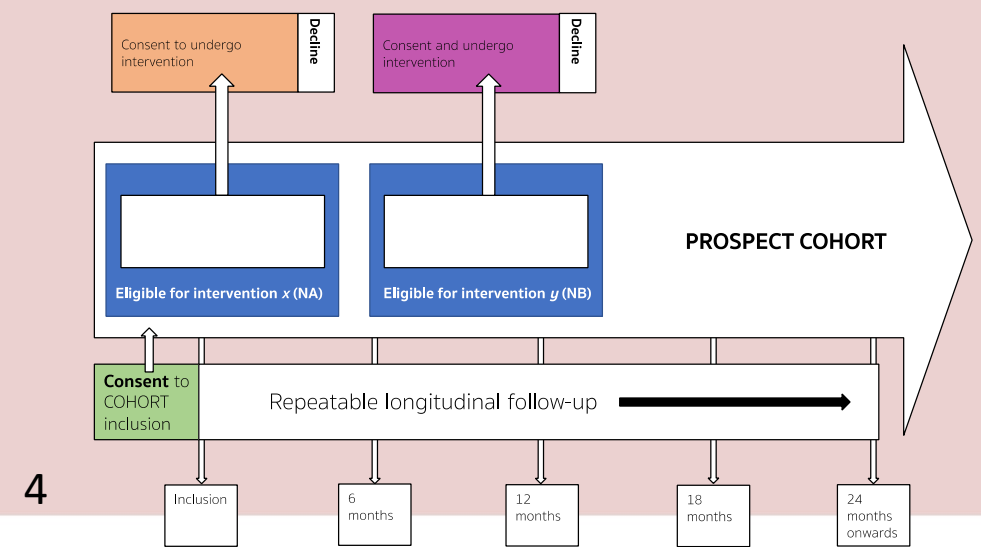
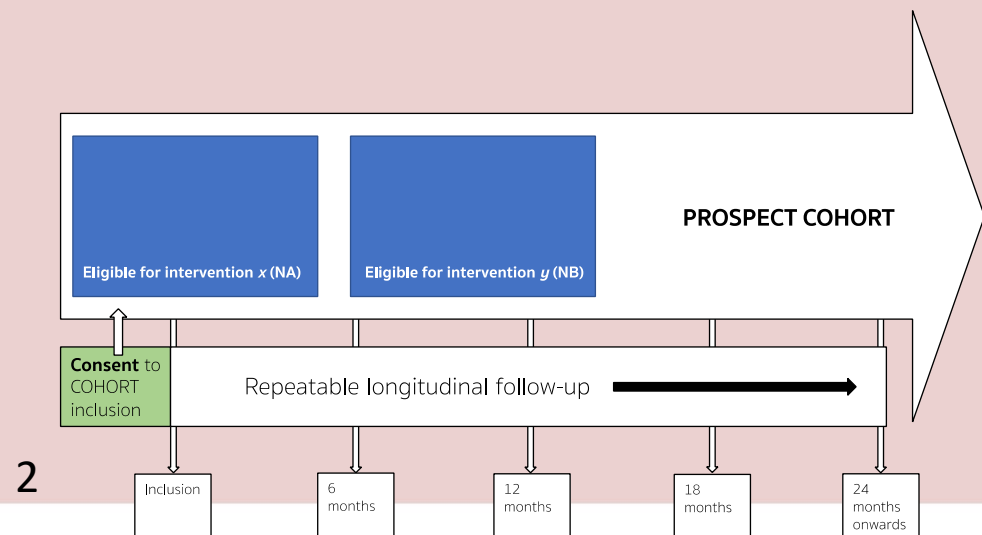
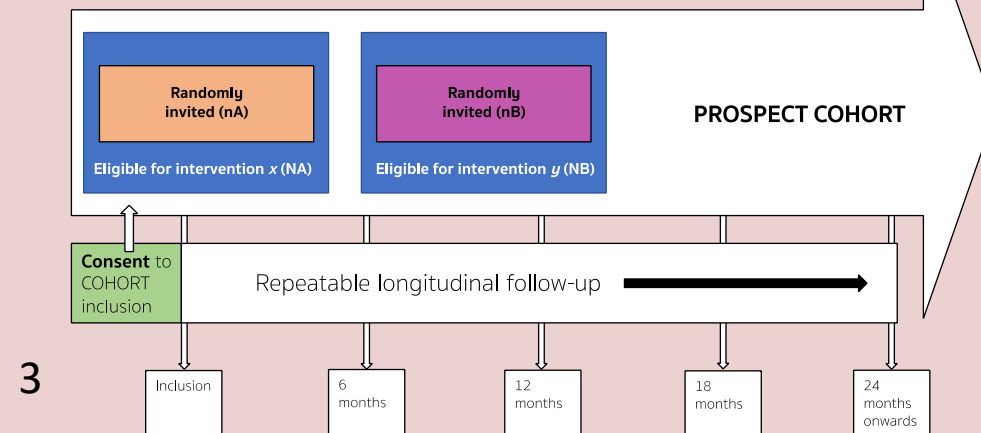
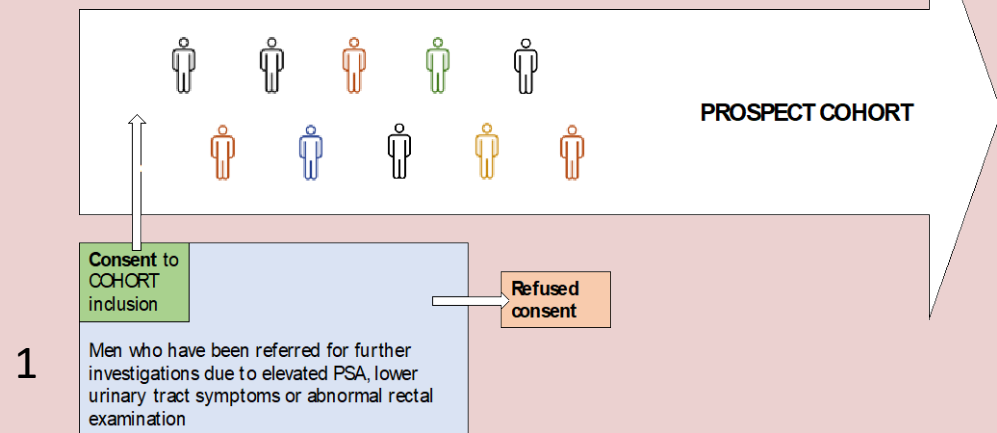
- Cohort Multiple RCT (cmRCT) or Trials Within Cohorts (TWICS) shows promise as an alternative.
- IP3-PROSPECT is a multicentre cmRCT
  - Designed to recruit a large heterogeneous group of men.
    - From which, eligible men can be randomly selected to consider testing a new intervention.



PROSPECT



-   
Join the PROSPECT cohort
-   
Receive regular follow up regarding your well being & prostate health
-   
You may be approached to consider new treatments or interventions as they arise



- Assess acceptability and feasibility of recruiting to the cohort.
- Recruitment target, recruitment rate
- PROMS return rate, data collection
- Patient & HCP interviews (Qualitative analysis)

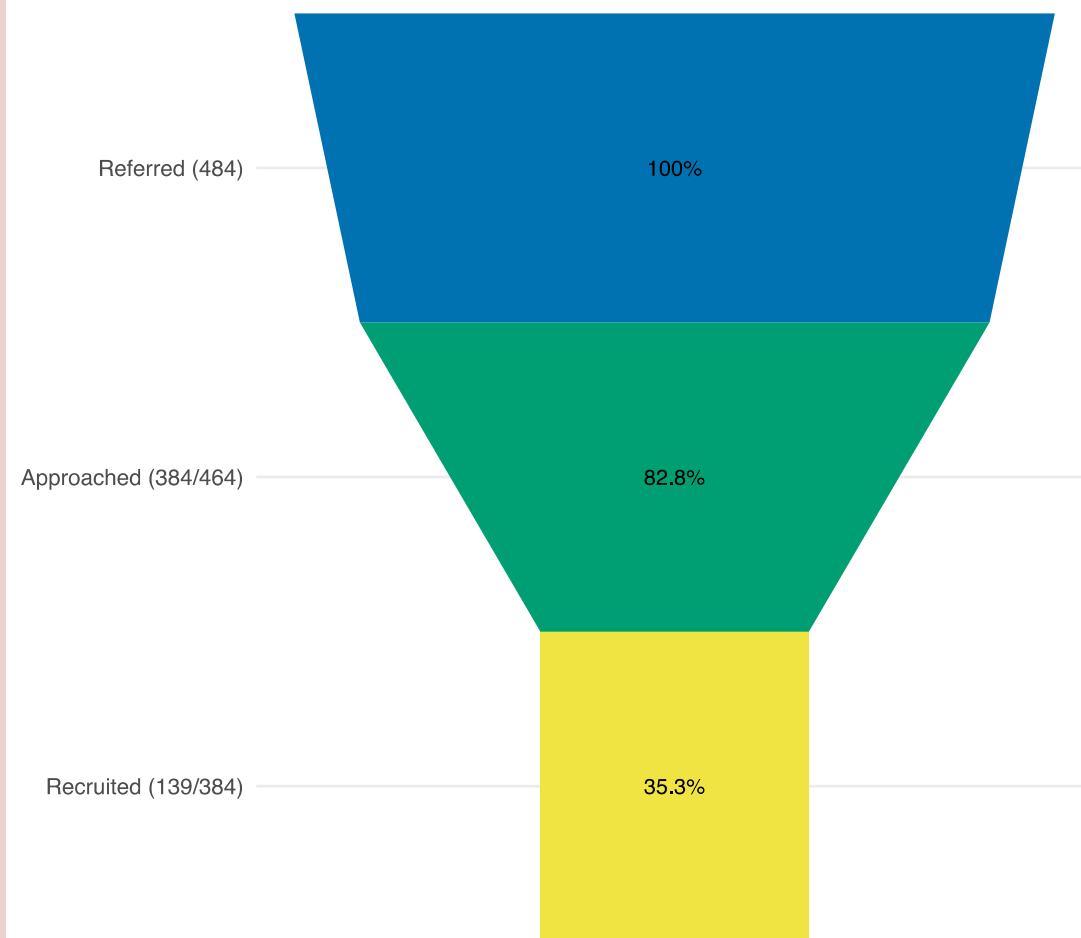
- **Inclusion Criteria**

- Patients aged 18 years old and over who are referred for investigations for urinary symptoms or elevated serum prostate specific antigen (PSA) levels or other risk factors for possible prostate malignancy.
- An understanding of the English language sufficient to understand written and verbal information about the trial and consent process.
- Estimated life expectancy of 5 years or more.
- Signed informed consent.

- **Exclusion Criteria**

- Patients who are unable to give informed consent.

## IP3-PROSPECT Recruitment Flow



Recruitment began in September 2020

Four recruiting sites

139 patients recruited

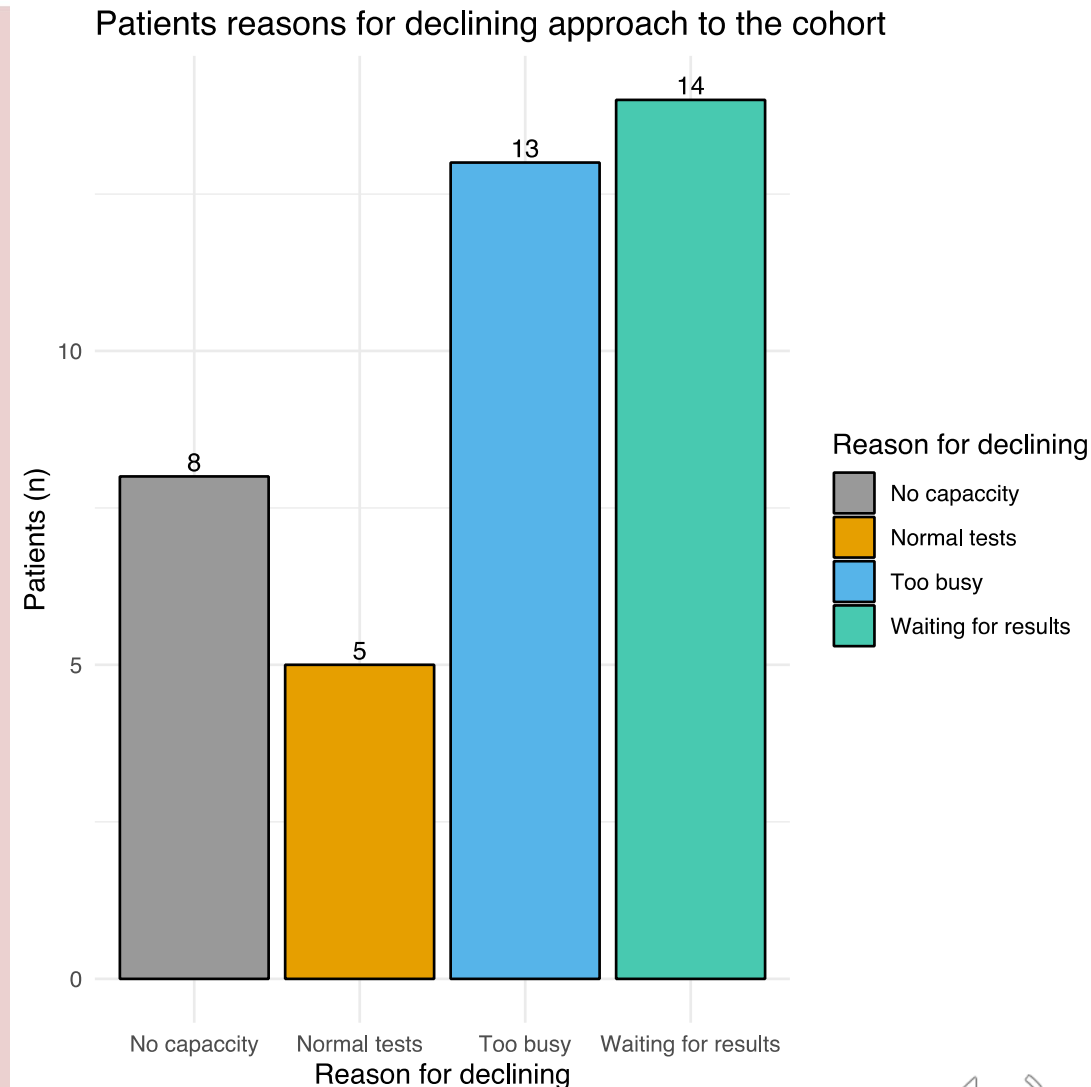
Recruitment rate 35.3%, “funnelling effect”

Data collection completeness >90% in all categories at each site

Visit	Questionnaire	Responded
0 (Baseline)	EQ-5D-5L, EPIC26, IPSS, IIEF-15	78.4%, 79.1%, 78.4%, 77.0%
1 (After Investigations)	EQ-5D-5L, EPIC26, IPSS, IIEF-15	69.1%, 69.1%, 69.8%, 69.1%
2 (6 months)	EQ-5D-5L, EPIC26, IPSS, IIEF-15	68.3%, 66.9%, 66.9%, 65.5%

PROMS return rates were good but fell over time  
Especially true in those with no cancer

- 10 patients agreed to interview at trial entry
- None withdrew
- Most patients joined for selfless reasons balanced against access to new / interesting treatments
- No issue with being a silent control or long-term follow-up
- Reasons for not joining more varied



- 10 HCPs agreed to interview
- Variation in roles (Surgeons, trainees, nurses, research managers)
- Not a “panacea”
- Pragmatism is a benefit, but some challenges remain.



- This is the first successful recruitment to a cmRCT in prostate cancer
- Interest is high amongst this patient group
- Aim is to use the platform as a vehicle to test novel interventions

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