

XXXIII CONGRESSO NAZIONALE AIRO

# AIRO2023

BOLOGNA,  
27-29 OTTOBRE 2023

PALAZZO DEI CONGRESSI

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

## PSMA GUIDED APPROACH FOR BIOCHEMICAL RELAPSE AFTER PROSTATECTOMY- (PSICHE) TRIAL (NCT05022914). DETECTION RATE AND TREATMENT DECISION AFTER 68GA-PSMA PET/CT WITHIN A PROSPECTIVE STUDY.

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## DICHIARAZIONE

Relatrice: Carolina Orsatti

- Posizione di dipendente in aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Consulenza ad aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Partecipazione ad Advisory Board: **NIENTE DA DICHIARARE**
- Titolarità di brevetti in compartecipazione ad aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**
- Partecipazioni azionarie in aziende con interessi commerciali in campo sanitario: **NIENTE DA DICHIARARE**

## Background

**Biochemical relapse (BR) after radical prostatectomy (RP) is currently managed with salvage radiotherapy (SRT) [1]**

**Prostate-specific membrane antigen positron emission tomography–computed tomography (PSMA PET/CT) radically changed this scenario [2]**

**EAU 2022 guidelines [3]: perform PSMA PET/CT with PSA >0.2 ng/ml if this will influence treatment decisions, but little is known about the clinical impact on treatment options**

**In order to evaluate the role of PSMA PET/CT imaging within a metastasis directed therapy framework, we designed a prospective trial.**

1. Thompson IM et al. AUA/ASTRO Guideline. J Urol. 2013 Aug.
2. Emmett et al. J Nucl Med 2017.
3. EAU Guidelines, EAU Annual Congress Amsterdam 2022.

## Materials and Methods

Prospective, observational, multicentre study

- RP ✓
- PSA  $\geq 0,2$  and  $\leq 1$  ng/ml

- PSA  $>0,1 \leq 16$  weeks after RP 
- ADT  $\leq 6$  months prior to enrollment

**Primary EP:** 2-yrs PFS (to death, BR or RR)

**Secondary EP:** OS, rPFS, 2-yrs QoL (EORTC QLQ-C30 and QLQ-PR25), AE CTCAE 4.0, impact of PSMA PET/CT on treatment decision (proportion of pts.), miRNA analysis.

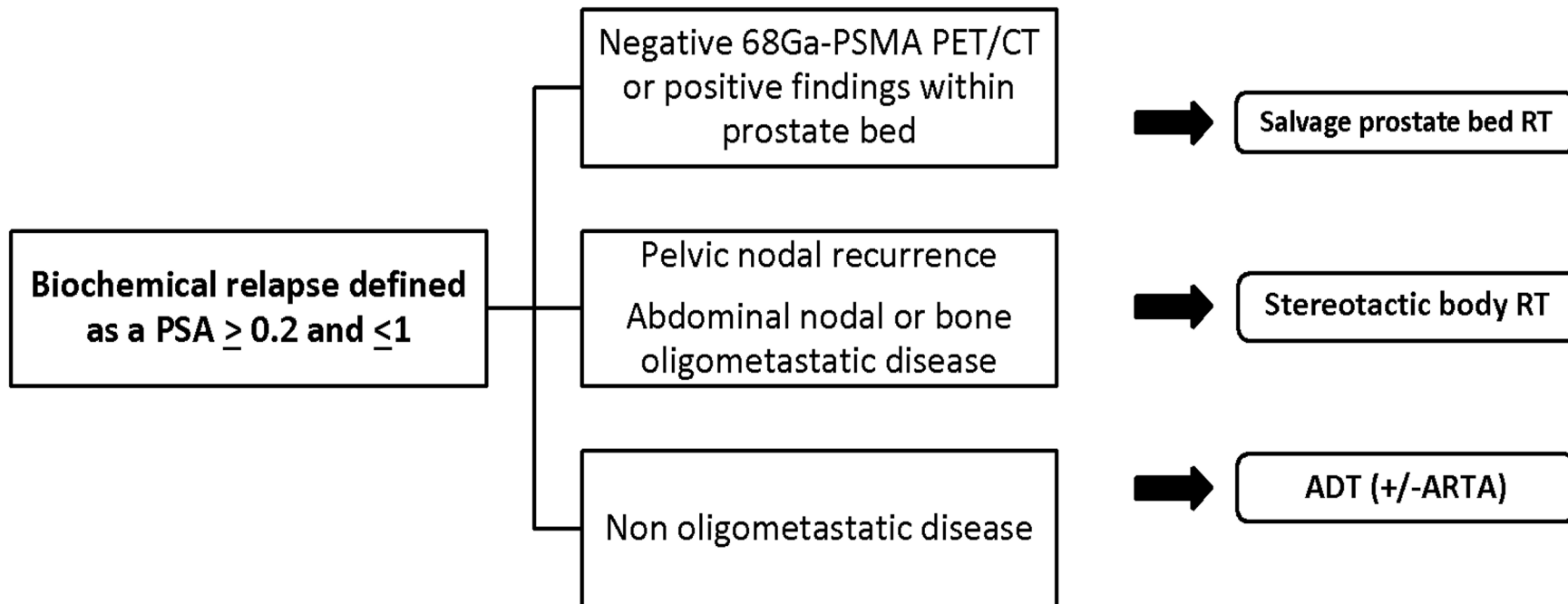
Enrollment started 19/03/2021, target 180 pts.

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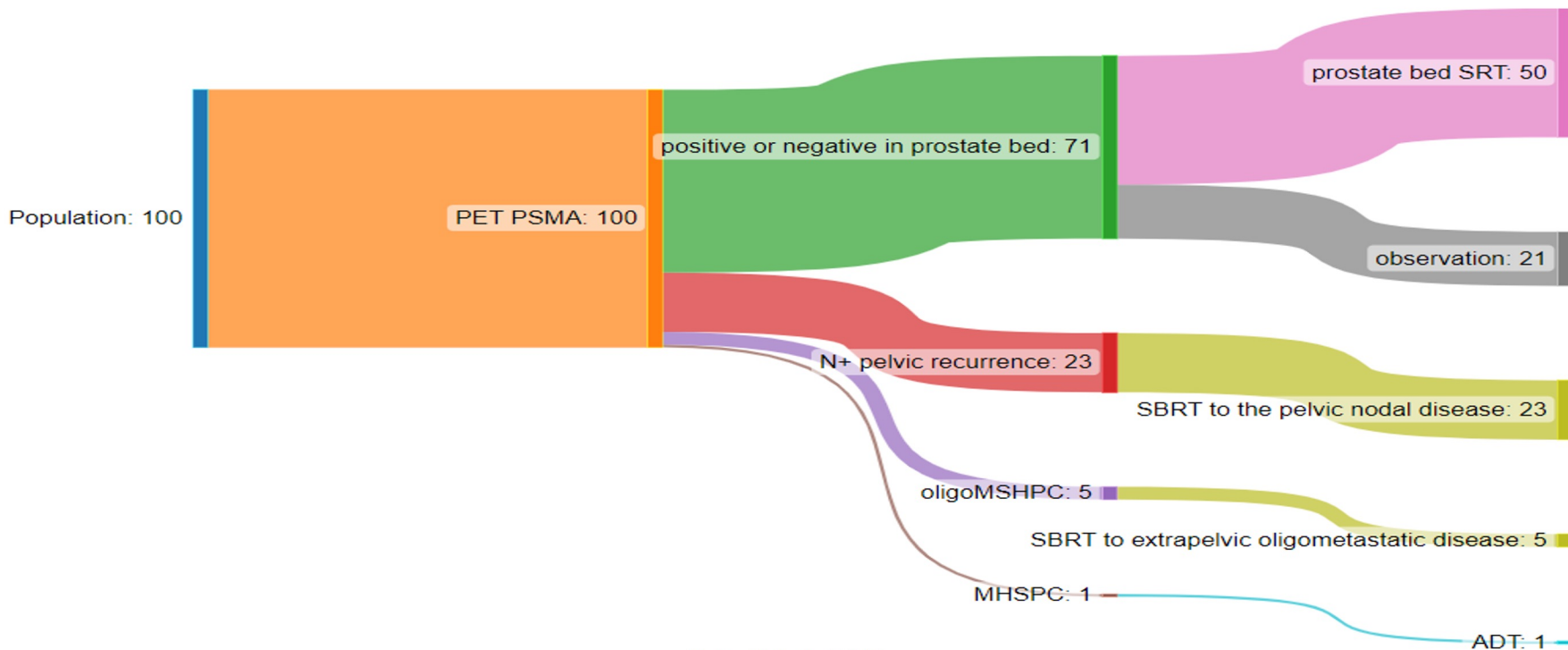


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## Procedures: Pre-defined treatment algorithm



## Results



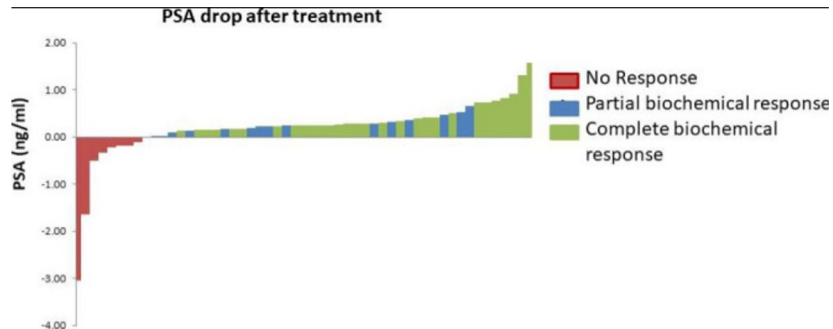
## Results

| Baseline characteristics    |                       |
|-----------------------------|-----------------------|
| Previous postoperative RT   | Yes: 28 (28)          |
|                             | No: 72 (72)           |
| Age (Median value, IQR)     | 68 (IQR 62-72)        |
| Baseline T stage (%)        | T2b-c: 27 (27)        |
|                             | T3a-b: 73 (73)        |
| Baseline N stage            | N0: 66 (66)           |
|                             | N1: 4 (4)             |
|                             | Nx: 30 (30)           |
| Margin status               | R0: 57 (57)           |
|                             | R1: 43 (43)           |
| Baseline ISUP pattern       | ≤3: 63 (63)           |
|                             | >3: 37 (37)           |
| Baseline PSA (median, IQR)  | 8 ng/ml (IQR 5.5-11)  |
| Baseline NCCN risk category | Low: 2 (2)            |
|                             | Intermediate: 21 (20) |
|                             | High: 77 (77)         |

At 3 months after treatment, **54.7%** of patients had a **complete biochemical response**.

Only **2 patients** experienced **G2 Genitourinary toxicity**.

**No G2 Gastrointestinal toxicity** was recorded.



## Conclusions

The results of **PSMA PET/CT imaging** provides an important and reliable means to **tailor treatment** in a significant percentage of the patient cohort studied;

Preliminary results from the first cohort of patients enrolled showed **promising biochemical outcomes**;

**PSICHE trial** could constitute a useful **prospective platform** to collect data within a current clinical scenario where modern imaging and metastasis directed therapy are available (translational research ongoing);

Detection of baseline expression of a specific panel of **miRNA** to evaluate correlation with **PSMA imaging outcomes**;

Study ongoing and first clinical outcomes awaited!



## Thank you for the attention!



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