ANZUP Cancer Trials Group Limited

GUIDE Trial News

www.anzup.org.au

Welcome to the first GUIDE newsletter

GUIDE opened its first site, Chris O'Brien Lifehouse NSW, on 18 November 2021. Last week, on 29 July 2022, we reached another important milestone - the first of 120 patients was enrolled at Kinghorn, St Vincent's Hospital NSW. Another four sites have been activated this year and there is one site expected to open in the coming weeks.

A huge ***thank you*** and ***congratulations*** to all involved for your hard work in reaching this milestone!

GUIDE is another exciting partnership between ANZUP and the Chris O'Brien Lifehouse.

Study Chair: Associate Professor Kate Mahon

"It's exciting to get the GUIDE study started to see if we can improve the way we give chemotherapy to men with advanced prostate cancer."

Study team introduction

Study Chair: Associate Professor Kate Mahon
Deputy Chair: Professor Lisa Horvath

ANZUP Team (study sponsor):
Chair: Ian Davis
CEO: Marg McJannett
Contracts and Finance: Thomas Cusick (trials@anzup.org.au)

Central Laboratory: Prostate Cancer Research Group
Garvan Institute of Medical Research
Contact: Nicole Yeung (N.yeung@garvan.org.au)

Contact us:
Email: Theresa.yeung@petermac.org which is the trial mailbox for all your study related questions or trials@anzup.org.au for any sponsor related queries.

Centre for Biostatistics and Clinical Trials (BaCT) - trial coordination:
Clinical Trial Project Manager – Theresa Yeung (Theresa.yeung@petermac.org)
Clinical Data Manager – Syafiqah Zulkefli (Syafiqah.zulkefli@petermac.org)
Statistician – Sophia Xie (Sophia.Xie@petermac.org)

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What is GUIDE?

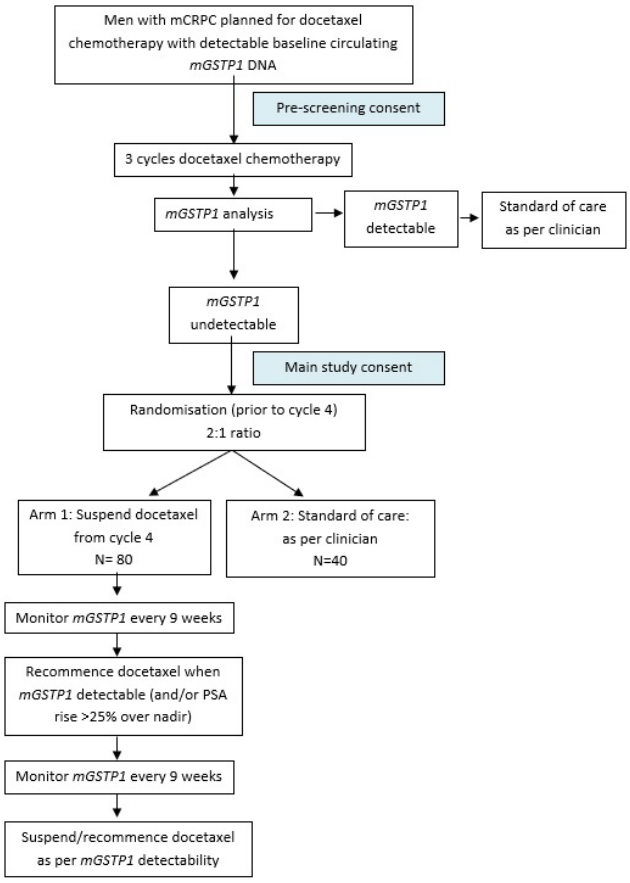
A randomised non-comparative phase II trial of biomarker-driven intermittent docetaxel versus standard-of-care (SOC) docetaxel in metastatic castration-resistant prostate cancer (mCRPC).

Aim - to evaluate the treatment outcomes of intermittent docetaxel guided by plasma mGSTP1.

Objectives – for Stage 1 feasibility:	
Primary	Number (%) of patients with undetectable mGSTP1 15 weeks after starting docetaxel treatment

Objectives – for Stage 2 - To assess amongst patients who have intermittent docetaxel:	
Primary	Radiographic progression free survival (rPFS)
Secondary	• Time on treatment holidays • Number of treatment holidays • Toxicity (CTCAE v5) • Patient reported outcomes • Overall survival • Health economic analysis

Study Schema:

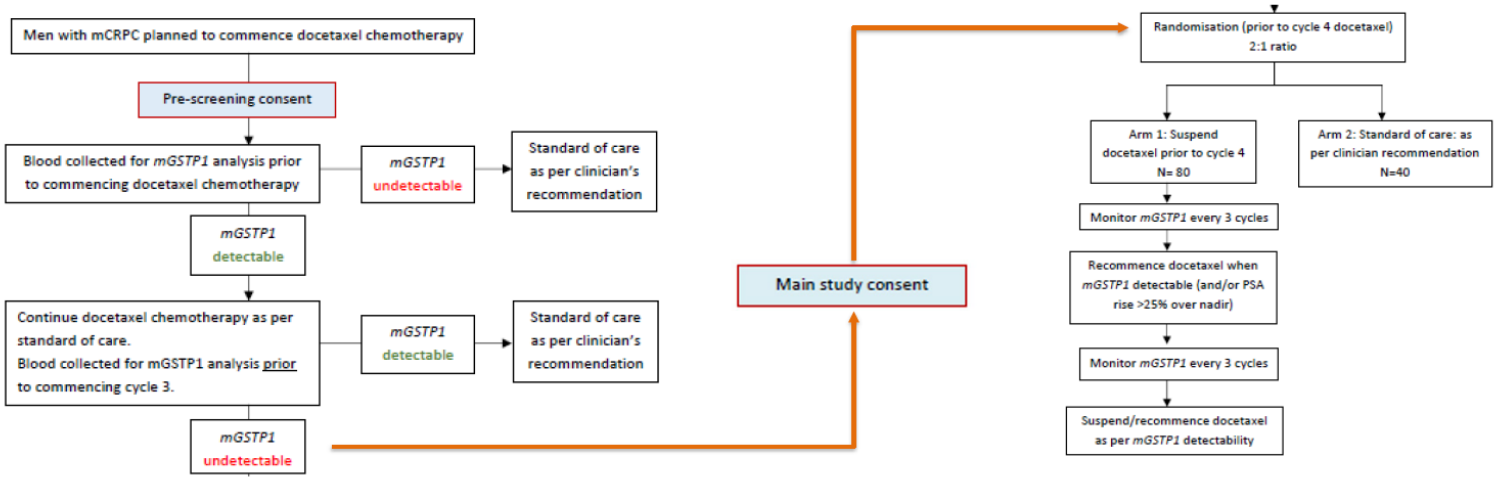


Recruiting sites

Current Active Sites	# Patient Screened	# Patient Registered as of 31 July 2022
Enrolment Target: 120 patients		
Chris O'Brien, Lifehouse, NSW (COL)	4	-
Concord, NSW		-
Kinghorn, St. Vincent's NSW (SVH)	2	1
Albury-Wodonga (BMO)		-
Goulburn (GVH)		-
Total		1

Pending site activation: Dubbo, NSW (DBH)

GUIDE patient enrolment process



Pre-screening phase

- Patients in pre-screening should not be entered or registered into the study database (Viedoc)
- Patients with undetectable mGSTP1 (blood collected prior to commencing cycle 3 of docetaxel) are eligible to screen for the main study

Screening phase

- Screening for the main study must be completed prior to cycle 4 of docetaxel
- Only enter patient into the study database (Viedoc) once all screening assessments have been completed and are deemed eligible by the investigator.
- Screen fails will not be captured in the study database (Viedoc)

Randomisation

- Randomisation of patients to the GUIDE study is to be completed via the study database (Viedoc)
- Patient will be assigned to;
    - Arm 1: suspend docetaxel prior to cycle 4 OR
    - Arm 2: standard of care: as per clinician recommendation

For any questions relating to this process, please contact the BaCT CTPM: Theresa Yeung (Theresa.yeung@petermac.org).

Data Management

A reminder that the following are required for every randomised patient and as per the GUIDE Site Source Data Verification Checklist:

- De-identified source documents are sent to BaCT within 5 business days of visit or report availability
- Ensure all patient reports are DE-IDENTIFIED and GUIDE patient registration number is visible on each page
- Ensure study visit data and data queries are entered and attended to in a timely manner

Please send documents to the BaCT Clinical Data Manager: Syafiqah Zulkefli (Syafiqah.zulkefli@petermac.org).

In partnership with:

Chris O'Brien Lifehouse

When it comes to cancer care, **choose hope.**

In collaboration with:

BaCT Centre for Biostatistics and Clinical Trials

Garvan Institute of Medical Research

GUIDE key contacts

- **Clinical trial operations, BaCT E:** Theresa.yeung@petermac.org
- **Coordinating PI: Kate Mahon E:** kate.mahon@lh.org.au
- **Sponsor queries (payments, contracts) E:** trials@anzup.org.au
- **Trial information:** https://anzup.org.au/clinical-trial/guide/