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# Pressurised Intra Peritoneal Aerosolised Chemotherapy (PIPAC) in the management of cancers of the colon, ovary and stomach: a randomised controlled phase II trial of efficacy in peritoneal metastases.



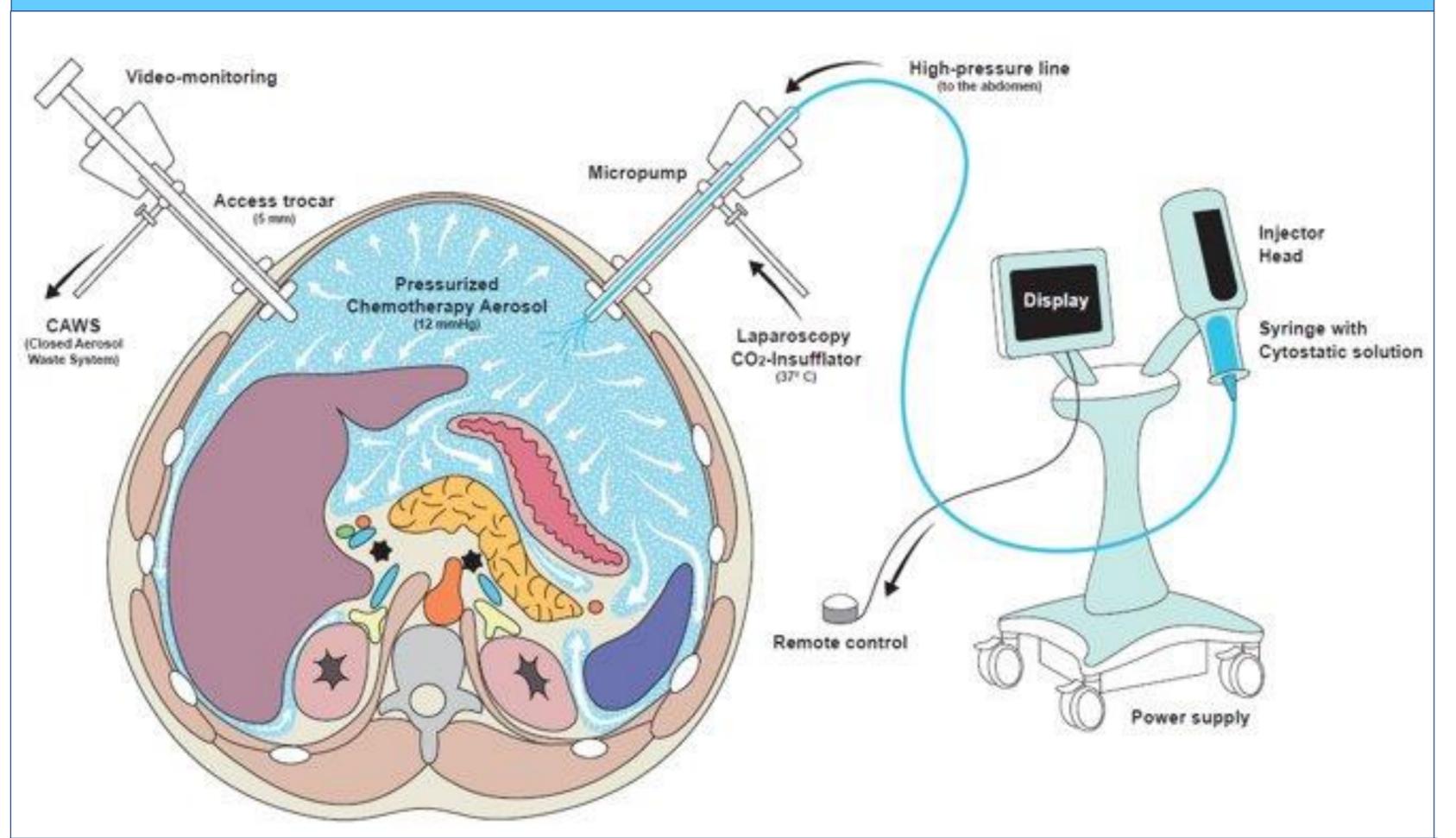
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#### AIMS

- To determine if PIPAC given with (colorectal, stomach) or instead of (ovarian) systemic anti-cancer therapy (SACT) improves peritoneal progression free survival compared to standard systemic anti-cancer therapy.
- PIPAC is emerging as a potential new strategy where aerosolised chemotherapy is delivered via keyhole surgery directly to the tumour site.

## PIPAC ILLUSTRATION



## **METHODS**

- This is a Phase II, unblinded, multi-centre, superiority, basket randomised control trial.
- Each cancer type will have individual eligibility criteria and protocols to allow for the necessary variations in treatment.
- Participants will be randomised in a 1:1 ratio to receive either standard SACT or a combination of standard SACT and/or PIPAC.
- We aim to recruit 78 colorectal, 66 ovarian and 72 stomach cancer patients over two and a half years.
- Follow up will last at least six months.

#### Patient with peritoneal metastases as a consequence of colorectal, ovarian or stomach Patient meets eligibility criteria for tumour type Patient does not consent Approached regarding registration prior to randomisation to randomisation Consent Data collection on reason for Clinician chooses chemotherapy regimen non-randomisation Randomisation: Randomise 1:1 PIPAC vs no PIPAC Colorectal (n=78), Ovarian (n=66), Stomach Arm 2: No PIPAC Arm 1: PIPAC Colorectal Ovarian Stomach SACT\* SACT\* PIPAC SACT\* SACT\* SACT\* PIPAC + SACT\* PIPAC PIPAC + SACT\* PIPAC SACT\* SACT\* SACT\* SACT\* SACT\* PIPAC + SACT\* PIPAC

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SACT\*

PIPAC

\* SACT = Systemic Anti-Cancer Therapy. Should be as per standard of care options listed within the PICCOS protocol. There are 2 or 3 weekly options for colorectal/ stomach groups, regimen given is chosen by treating clinician, ovarian SACT is 4 weekly.

Follow Up: Nurse telephone call, CT scan and CEA/Ca125 blood test

(colorectal/ovarian group only) every 2 months for the first year and

every 3 months thereafter. EORTC QLQ C30 questionnaire every 4

### **CONTACT US**

SACT\*

PIPAC + SACT<sup>8</sup>

PIPAC + SACT\*

SACT\*

SACT\*

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TRIAL SCHEMA

 If you would like your centre to take part in PICCOS either as a recruiting centre or PIPAC delivery centre, please contact PICCOS@cardiff.ac.uk

#### CONCLUSION

This is the first UK randomised controlled trial assessing the efficacy and impact of quality of life of PIPAC in the management of peritoneal metastases. PICCOS aims to provide high quality evidence to guide clinical practice and further research. The trial is now recruiting.













