

AGO OVAR 19

TRIAL ON RADICAL UPFRONT SURGERY IN ADVANCED
OVARIAN CANCER INCLUDING EVALUATION OF
FRAGILITY AND LONG TERM QUALITY OF LIFE

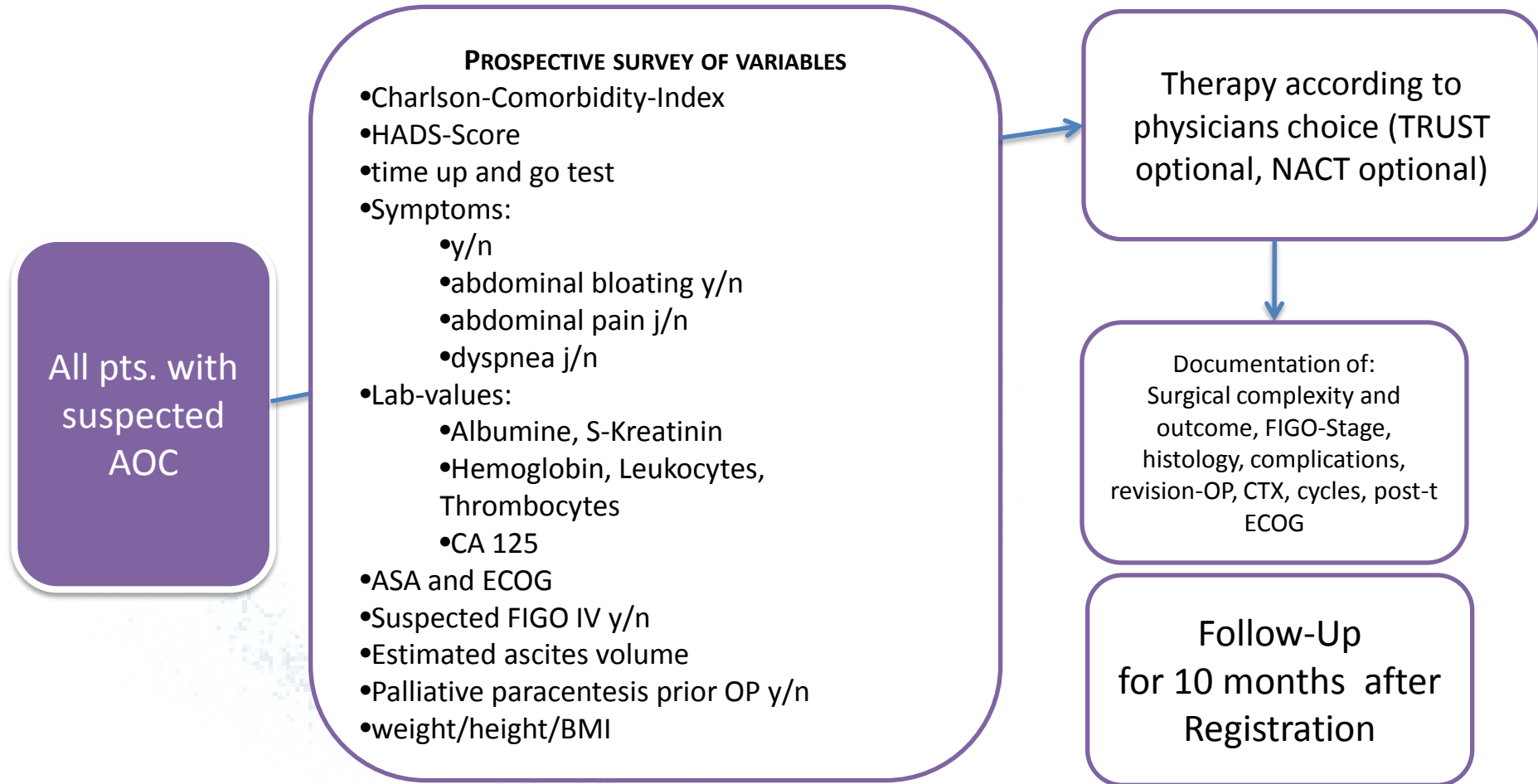
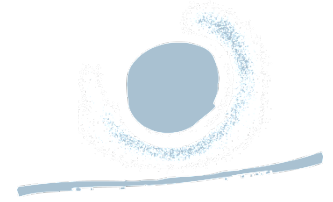
AGO OVAR 19 - QoL longitudinal with specific topics for TRUST

FRAGILE: prim. Endpoint: 10-PFS



Identifying pts without benefit from standard OP → CTX

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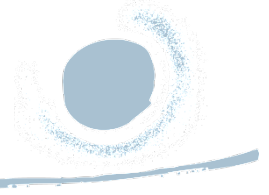


Primary endpoint: identification of fragile pts without benefit from standard OP → CTX (=progression/death within 10 months)

Secondary endpoint: 3 months survival, feasibility (time to 1st cycle, cycles, residual tumor, FIGO-Stage, ECOG after 6 months, 6 months PFS, revision surgery)

Identifying pts without benefit from standard OP → CTX

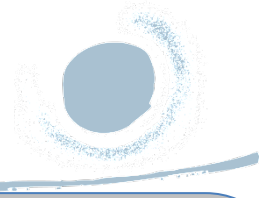
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Primary objective:

- to describe a multiple logistic regression model to predict the unfavorable event of death or progression within 10 months after diagnosis of primary ovarian cancer using covariates available at the time of diagnosis.
- The rule of 10 states that 10 events are needed for each estimated regression coefficient
 - The predictors mentioned above lead to a number of 20-28 potential covariates in the model (some of the predictors might need more than one coding variable).
 - We assume that only about 10 covariates will be included in the final model if forward variable selection is applied.
 - Data from QS-OVAR from 2004 and 2008 showed a PFS rate of ca. 74% at 10 months (unpublished data). Hence, with 440 patients, about 110 events are expected, giving robust odds ratio estimates for up to 10 covariates (plus the estimate of the baseline proportion).

PRO endpoints in AGO OVAR 19



Start: Q4 2014

Recruitment: N=440 patients within 15 months.

Instruments:

- EORTC QLQ-C30 and QLQ-OV28

Time points:

- at baseline and then every 3 months (+/- 30 days) until month 36
- In patients without progression 18 months after end of chemotherapy (not maintenance) the interval is extended to 6 months. In case of a new progression an additional QoL assessment have to be performed within 30 days and repeated in pre- defined 3 months intervals calculated from registration.

For all patients (surgical and extended part)

- Co-Primary: Long term Quality of Life (QoL) to describe the influence of treatment and course of disease on quality of life

For TRUST-Pts.

- Primary: General Health status 24 months after randomization (PDS vs NACT)