Patient Related Outcomes in Cancer Patients in Croatia

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BACKGROUND

Accurate evaluation of symptom intensities is essential for optimal cancer care and improving the quality of life of patients.
An inappropriate interpretation of symptoms may lead to treatment outcomes failure, overdose of medication, or may leave the patients undertreated.
However, the perception of symptoms can vary between the treating physician and patient.
Physicians appear to underestimate the patient symptoms. And this variation in the perception of side effects can lead to wrong assumptions and subsequent treatment changes, affecting treatment effectiveness and quality of life.
There is growing interest to enhance symptom monitoring during routine cancer care using patient-reported outcomes, leaving open the question of whether the benefits of systems to reveal self-reports outweigh their added cost.
There are several tools for assessment of symptoms in oncology. In cancer treatment clinical trials, the standard source of adverse symptom data is clinician reporting by use of items from PRO-CTCAE, developed by NCI.

METHODS

Patients initiating chemotherapy at General Hospital Pula Oncology clinic for advanced or metastatic gastrointestinal, lung, breast, genitourinary, or gynecologic cancers will be enrolled in a nonblinded, prospective trial of self-reporting of symptoms, compare with usual care.
Patients receiving chemotherapy and their clinicians will be independently asked on the same day to complete 10 symptoms (including fatigue, pain, nausea, vomiting, diarrhea, dysgeusia, appetite, sleep disturbance, fever and hair loss).
Participants will remain on study until discontinuation of cancer treatment, withdrawal, or death.
All participants will provide written informed consent and followed for up to 28 months or until death.

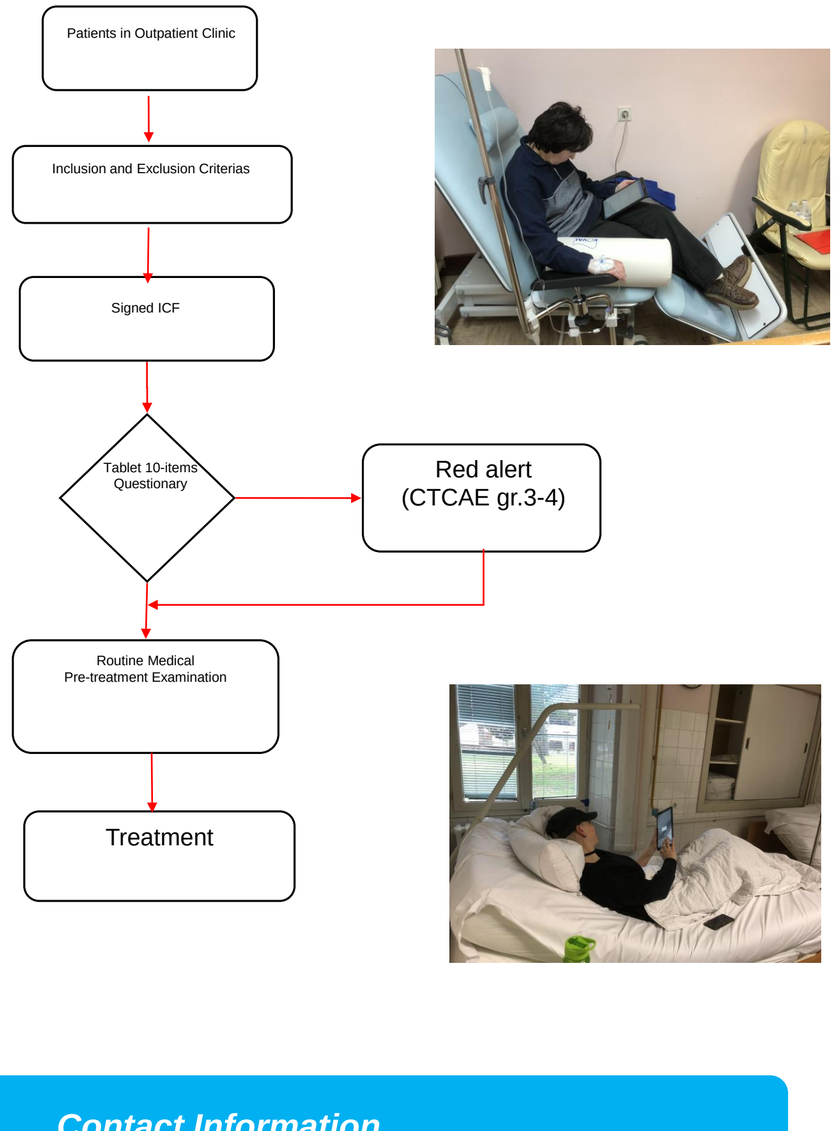
OBJECTIVES

PRIMARY ENDPOINT

To address these questions, we conducted a single-center prospective trial to test whether systematic tablet computer-based collection of patient-reported symptoms during chemotherapy treatment, with automated alerts to clinicians for severe adverse events (grade 3-4) will change in questions score at 6 months compared with baseline.

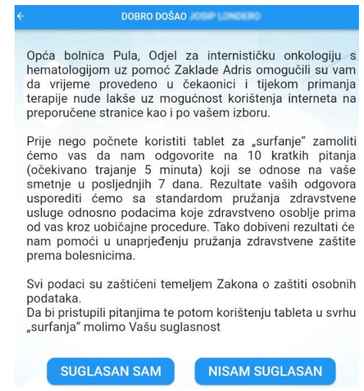
SECONDARY ENDPOINTS

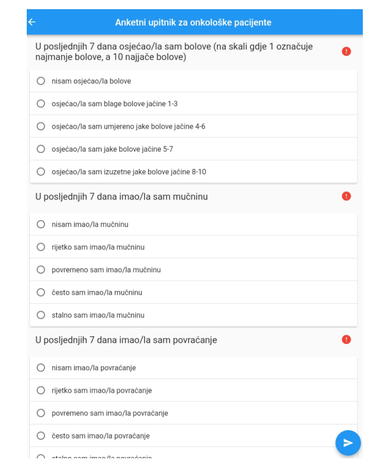
Secondary endpoints will include unscheduled clinic visits, and survival



STATISTICS

To compare how patient's vs clinician's reports relate to clinical events, a time-dependent Cox regression model adjusted for covariates including age, sex, cancer type, and education level will be used to measure associations between reaching particular grade severity thresholds with the risk of death and unscheduled clinic visits.





ACCRUAL

Study Activation April 2019
Accrual as of May 2019;
Anticipated accrual closure date 2020
Anticipated final analysis: 2021.

REFERENCES

1. Basch E, et al. *J Natl Cancer Inst*. 2009;101:1624-32.
2. Laugsand EA, et al. *Health Qual Life Outcomes*. 2010;8:104.
3. Kotronoulas G, et al. *J Clin Oncol*. 2014;32:1480-501.
4. Basch E, et al. *JAMA*. 2017;318:197-8.
5. Holch P, et al. *Ann Oncol*. 2017;28:2305-11.
6. Velikova G,et al. *J Clin Oncol*. 2004;22:714-724.
7. Absolom K, et al. *BMC Cancer*. 2017;17:318.
8. Dudgeon D, et al. *Psychooncology*. 2012;21:357-364.

Contact Information

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