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Digital monitoring of bladder cancer patients (eBladder)

Submission date 30/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/12/2023	**Overall study status** Completed	
Last Edited 02/10/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
In oncology, the impact of both the disease and treatment on patient's daily lives is traditionally monitored through anecdotal information during scheduled visits and hospital admissions. However, this provides limited data on well-being during treatment and recovery. With the increasing use of wearable devices and smartphones, there's an opportunity to objectively quantify parameters like steps and heart rate, providing real-time patient data and a more realistic measure of the disease burden. This study aims to assess the feasibility of continuously monitoring cancer patients using the Trial@home platform and correlating digital measures between scheduled visits with standard symptom registrations to generate new biomarkers reflecting the treatment's impact on daily life and quality of life.

Who can participate?
Patients aged 18 to 100 years old with a pathologically confirmed diagnosis of bladder cancer

What does the study involve?
Testing the feasibility of a digital remote monitoring platform (Trial@home). This involves continuous and passive data collection from a smartwatch and phone data usage. Participants will be expected to undertake daily measurements of their body temperature and complete a urinary frequency log, weekly weight measurement and 4-weekly completion of the quality-of-life questionnaire and a urinary symptom questionnaire.

What are the possible benefits and risks of participating?
As this is a non-therapeutic trial, subjects are not expected to obtain direct health benefits from the study participation. However, subjects could benefit from getting a better insight into their vital signs and other parameters, and provide valuable information regarding the impact of the disease on their daily life during the treatment period. There are no significant health risks associated with the study assessments. Furthermore, we do not expect any risks regarding the psychological or social state of study participants. The burden of the study participants is estimated to be low. Except for the smartwatch and phone usage assessments, for which data will be collected continuously, all study-mandated actions can be performed at the subjects'

home or hospital room. No invasive procedures are included in this study. Collected digital data will pass through adequately protected data servers, preventing privacy infractions. Furthermore, the study assessments will not be used to influence the clinical decision process.

Where is the study run from?
Amsterdam UMC, Amsterdam (The Netherlands)

When is the study starting and how long is it expected to run for?
January 2023 to March 2026

Who is funding the study?
The Dutch Cancer Society (KWF Kankerbestrijding Grant number: 13144) (The Netherlands)

Who is the main contact?
A.D. Bins, MD, PhD, clintrials@chdr.nl (The Netherlands)

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Additional identifiers

Protocol serial number
CHDR2023

Study information

Scientific Title
An observational, non-interventional cohort study to monitor physical and social activity of bladder cancer patients during treatment with curative intent by using conventional and digital methodology

Acronym
eBladder

Study objectives
The expanding use of wearable devices and smartphones offers new opportunities to continuously assess performance status and quality of life with real-time patient data. This way, the burden of disease is measured more realistically, objectively, and more frequently, in their environment, and on an individual level. The Trial@home platform developed by the Centre for Human Drug Research (CHDR) allows the collection of continuous data from patients through various devices, such as the Withings HR Smartwatch, Withings Scale+, Withings Thermo and Withings Sleep. In addition, the platform allows the unobtrusive collection of data from smartphone sensors via the MORE app. Finally, through the electronic patient-reported outcome (ePRO) module, the ePRO app, patients can answer questionnaires digitally and from home. This study aims to determine the feasibility of monitoring bladder cancer patients with the Trial@home platform.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/01/2023, Medische Ethische Toetsingcommissie Amsterdam UMC (De Boelelaan 1118, Amsterdam, 1081 HV, Netherlands; +31204445585; metc@amsterdamumc.nl), ref: 2022.0634

Primary study design
Observational

Study design
Observational non-interventional cohort study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Bladder cancer

Interventions

This is an observational, non-interventional cohort study to monitor social activity, physical activity, heart rate, weight, temperature, and sleep of bladder cancer patients receiving care at Amsterdam Universitair Medische Centra (Amsterdam UMC) and Leids Universitair Medich Centrum (LUMC). After obtaining written informed consent, patients will be provided with a Withings Steel HR smartwatch, a Withings Body+ Scale, a Withings Thermo, a Withings Sleep, and if necessary, a smartphone.
Three apps will be installed on the smartphone (the patient's or the one provided by CHDR):
1. The "Health Mate" application, is used to collect the Withings data.
2. The "CHDR MORE" application, is used to monitor social activity on the phone and transfer the data to the CHDR server. This is only available for smartphones with an Android operating system version 7.0 to 11.0.
3. The "ePRO" application, which will be used to fill in the questionnaires.
If the patient has an incompatible smartphone, one will be provided to download the required apps. However, in these cases, the social activity (phone log and app usage) via the MORE app will not be collected because there will be no representative smartphone use.
Subsequently, an explanation is given about using the devices and the applications. After 48 hours the study coordinator contacts the participant to ensure he or she is connected properly to the ambulatory monitoring platform. Any immediate questions regarding using the devices and apps will be resolved. The research team will be available to provide technical assistance for the duration of the study. The measurements from the study devices will start with the allocation of study devices that will take place on the day of inclusion, but for the standardized analysis, only the data from 2 weeks before the beginning of treatment will be considered. Patients will be instructed to wear the smartwatch as much as possible during waking hours and sleep and to use their smartphones as usual. They will also be asked to log in to the ePRO Urinary frequency log every time they urinate in real-time and to measure their temperature every morning with the Withings Thermo. They will also be asked to measure their weight weekly with the Withings Body+ Scale, to synchronize their smartwatch using the Health Mate app on the smartphone, and to complete the EORTC QLQ-C30 via the ePRO app. Every 4 weeks since baseline, the patients will be asked to fill in the IPSS via the ePRO app. At the end of the study, the patients are asked to hand in their devices and to fill in an experience and subjective burden questionnaire to evaluate the usage of the devices.
After inclusion, the patient will continue until the end of the study or until the patient withdraws consent. The study population are patients with diagnosed bladder cancer, for which different treatment options according to their pathological classification and the treatment they are receiving:
1. NMIBC treated with intravesical instillation.
2. MIBC treated with radiochemotherapy with or without immunotherapy.
3. MIBC treated with cystectomy with or without neoadjuvant chemotherapy.
4. NMIBC treated with TURBT, without adjuvant therapy.
Every group will include a baseline period of 2 weeks, a treatment period which depends on the duration of the treatment per group but is of a minimum of 6 weeks and a maximum of 24 weeks, and a follow-up period of 4 weeks. The baseline period is considered to be the 2-week period before the start of the treatment. The beginning of treatment is defined as the first session or intervention of their respective follow-up treatment (intravesical instillation, radiochemotherapy or cystectomy). The end of treatment is defined as the last treatment session or intervention. If a patient is identified and interested in participation before the TURBT, there is a possibility to start earlier, so the differences pre- and post-TURBT can also be included in the study. For this, an extra 2-week period will be added, the "pre-TURBT period". This will provide additional baseline information for pre- and post-TURBT. If the time between the TURBT and the beginning of treatment is more than 2 weeks, the data will still be collected but for the analysis only 2 weeks before treatment will be considered as baseline period. In case there is no treatment started other than TURBT, the patient can be monitored for 12 weeks

(group 4).
Data will be collected from the patient's medical file from their corresponding hospital (Amsterdam UMC or LUMC). The parameters collected from the patient's medical file will be: treatment and dosing days, number of treatment interruptions (and reason), number of emergency room visits (and reason), number of planned and unplanned hospitalizations (and reason, date, length), adverse events, performance status (ECOG) and radiological evaluations (and date). All patients will receive standard best-care treatment during the study. The use of the comprehensive ambulatory monitoring platform is in addition to the standard care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Trial@home platform

Primary outcome(s)
The following primary outcome measures are assessed to determine the feasibility of monitoring bladder cancer patients with the Trial@home platform:
1. Smartwatch wear-time measured using the amount of time (hours) in a complete day (24 hours) that the participant wears the Withings Steel HR smartwatch. This is calculated by the amount of time that the device registers a heart rate. Based on previously published feasibility studies, patients wearing the device for >50% of the observation period will be considered as feasible.
2. Compliance rates (questionnaires) measured using the EORTC QLQ-C30 and International Prostate Symptom Score (IPSS) questionnaires, defined as the completion of at least 90% of the total of questions. Compliance rates of ePRO vary widely in previous literature, from 60 to 97%. Based on these, for the electronic questionnaires (EORTC QLQ-C30 and IPSS) a compliance rate of at least 75% from the scheduled assessments, will be considered as feasible.
3. Compliance rates (Thermo) measured using compliance with daily temperature measurements, calculated by the number of completed temperature measurements divided by the total amount of days in the observation period. No cut-off points for feasibility have been established previously. The compliance rate with vital signs measurements varies between 72-85%. Therefore, a compliance rate of at least 75% will be considered as feasible.
4. Compliance rates (Body+) measured using compliance with weekly weight measurements, calculated by the number of completed weight measurements divided by the total amount of weeks in the observation period. To establish a cut-off point for feasibility, the same principle as for temperature will be applied (see previous point). Therefore, a compliance rate of at least 75% will be considered as feasible.
5. Compliance rates (Urinary frequency log) measured according to a weekly question regarding compliance: 'How many times on average per day did you miss a registration this week (not including the ones filled-in late)?', being the possible answers: (a) I never missed a registration, (b) I missed registration on average 1 time or less per day, (c) I missed registration on average 2 times per day, (d) I missed registration on average 3 or more times per day. A compliance rate of at least 75% of answers (a) or (b) for the whole study period will be considered feasible. There are no published studies over an electronic module for a real-time patient-reported urinary log to quantify the daily urinary frequency.

Key secondary outcome(s)

The following secondary outcome measures are assessed to correlate social, physical, and physiological data of bladder cancer patients measured using data collected from the Trial@home platform for the duration of the study, the quality-of-life questionnaire (EORTC QLQ-C30) collected weekly and the performance status score:
1. Physical activity: step count, relative location
2. Social activity:
2.1. Phone usage (length of call, last 3 digits of phone number, number known/unknown)
2.2. App usage (categories of apps, start time, running in background/foreground)
2.3. Relative location
3. Weight (kg)
4. Body composition (%)
5. Temperature (°C)
6. Sleep pattern: sleep time, time in bed, sleep phases
7. Heart rate (beats per minute)
8. Urinary frequency (number of urinations per day and night)
9. EORTC QLQ-C30 scores
10. International Prostate Symptom Score
11. Treatment and dosing days
12. Number of treatment interruptions (and reason)
13. Number of emergency room visits (and reason)
14. Number of planned and unplanned hospitalizations (and reason, date, length)
15. Adverse events
16. Performance status (ECOG)
17. Radiological evaluations (and date)

Completion date
15/03/2026

Eligibility

Key inclusion criteria
1. Able to provide written informed consent
2. Patients suspected of or with a pathologically confirmed diagnosis of bladder cancer, with a predominant type of urothelial carcinoma or squamous cell carcinoma
2.1. Before or after undergoing TURBT
2.1. Before starting the rest of their treatment
3. ≥ 18 years at screening
4. Can communicate well in Dutch with the investigator and willing to comply with the study instructions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Key exclusion criteria
1. Permanent and temporary alterations on the wrist, including tattoos
2. Inability to wear or use wearables and other digital devices
3. Inability or limitations to walk or move at screening, or use of walking aids
4. History of allergy to surgical steel

Date of first enrolment
01/02/2023

Date of final enrolment
15/01/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
The Centre for Human Drug Research
Zernikedreef 8
Leiden
Netherlands
2333 CL

Study participating centre
Amsterdam UMC
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV

Study participating centre
Leids Universitair Medisch Centrum
Albinusdreef 2
Leiden
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2333 ZA

Sponsor information

Organisation
Amsterdam University Medical Centers

ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
Research organisation

Funder Name
KWF Kankerbestrijding

Alternative Name(s)
Dutch Cancer Society, Dutch Cancer Society (KWF Kankerbestrijding), KWF, DCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date