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Effects on health following collapse during marathon running

Submission date
04/12/2011

Recruitment status
No longer recruiting

Registration date
16/01/2012

Overall study status
Completed

Last Edited
20/12/2017

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
To investigate the immediate and short term effects on health for runners who collapse during Marathons. Marathon runners may collapse for a variety of reasons, including loss of muscle tone at the end of exercise (exercise associated collapse), imbalances in the levels of salts in the blood, and exertional heat stroke (EHS). EHS is a life-threatening illness with a very high core body temperature, above 40 degree celsius, associated with abnormal brain function. Up to 10% of runners with EHS may die. Marathon runners may also experience a variety of symptoms, including confusion, memory and balance problems, for weeks after a marathon.
If a runner experiences EHS, the temperature should be reduced to normal as soon as possible. The progression of the disease is primarily related to the initial care provided to the casualty. Medical teams at the event itself are therefore recommended to immediately identify and treat these serious conditions to reduce the complications from the collapse. Basic blood test results should be immediately available to the clinical team. For every 10,000 marathon runners, approximately 20 collapses will require intensive road-side assessment, monitoring and treatment by these teams. The majority of these cases will be able to be discharged home direct from the event, without the need for hospital treatment. If this medical service were unavailable at Marathons, then the local Emergency Department (ED) services would be required to treat these patients. The delay in treatment may cause additional complications. In the USA, patients with EHS are often admitted to hospital for 72 hours.
The medical team at the Brighton Marathon provides immediate treatment, invasive monitoring and point of care blood tests for all collapsed runners. If after a period of treatment and observation the medical team feels that the patient is safe to be discharged home, without the need for hospital admission, discharge advice and instructions are given. Collapsed runners are advised to see their general parctitioner (GP) within 48-72hrs for a test of their urine, and to repeat blood tests. This is to ensure that they haven't developed short term kidney complications.
The aim of this study is to obtain blood results taken on the day and at follow-up as part of good practice. In addition we would ask the runner if they would be willing to complete a questionnaire to investigate any immediate and short-term physical, neurological and psychological effects following collapse during a marathon.

Who can participate?
Both male and female runners old enough to participate in the marathon who collapse at the 2012, 2013 and 2014 Brighton marathon and require treatment by the on-site medical team and willing to participate in the study

What does the study involve?
The study will not change the participants treatment, but will ask if participants will give permission to the research team to check the records and analyse clinical information and investigations performed by the medical team at the marathon and by their GPs after the marathon. In addition the runner will be asked to fill in a short questionnaire asking questions about their health in the first week following the marathon and again at 3 months following the marathon.

What are the possible benefits and risks of participating?
Participants are unlikely to benefit directly from the study, but the information obtained will be used to gain more understanding about runners who collapse, and may improve treatment for runners in future marathons. The same medical treatment and follow-up care will be provided whether runners are in the study or not. No extra blood tests are needed for the study. Runners in the study will only be required to complete 2 short questionnaires, which should not be hard for the runners. The results of the blood tests and the questionnaires will be anonymised.

Where is the study run from?
Worthing Hospital (UK).

When is the study starting and how long is it expected to run for?
The study ran over the 2012, 2013 and 2014 marathons.

Who is funding the study?
We expect the study to have minimal costs, which will be met by the research team and by Brighton Marathon.

Who is the main contact?
Helen Evans, Research Governance Manager
helen.evans@wsht.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Richard Venn

Contact details
Western Hospitals NHS Trust
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1.0

Study information

Scientific Title
Effects on health following collapse during marathon running: a prospective observational study

Study objectives
Marathon runners who collapse during the marathon may experience physical and neuro-cognitive symptoms which may persist for several months. Little is known about these or the biochemical changes seen following a collapse.

On 28/07/2015 the overall trial end date was changed from 30/07/2012 to 30/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Portsmouth, 21/01/2013, REC ref: 12/SC/0048

Study design
Observational prospective study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Collapsed marathon runners

Interventions
The runner will be asked to fill in a short questionnaire asking questions about their health in the first week following the marathon and again at 3 months following the marathon.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Descriptive statistics to describe:
1. Demographics of runners who collapsed at the marathon including relevant marathon-training history, fluid & dietary management, comorbidities & medication history
2. Diagnosis and management required by the Intensive Care medical service at the marathon
3. Biochemical changes at the marathon & follow up
4. Health questionnaires at approximately 1 week & 3 months following the marathon
5. Any medical intervention at follow up required

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/04/2012

Completion date
30/07/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/07/2015:
Runners who collapse at the 2012, 2013 and 2014 Brighton marathons and require treatment by the on-site medical team

Previous inclusion criteria:
Runners who collapse at the 2012 Brighton marathon and require treatment by the on-site medical team

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/04/2012

Date of final enrolment
15/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Western Hospitals NHS Trust
Worthing
United Kingdom
BN11 2DH

Sponsor information

Organisation
Sussex NHS Research Consortium (UK)

Sponsor details
c/o Helen Evans
Research Governance Manager
Sussex NHS Research Consortium
Worthing
United Kingdom
BN11 2DH

Sponsor type
Government

Website
http://www.westernsussexhospitals.nhs.uk/about-us/worthing-hospital/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Publication and dissemination plan
We have written up and submitted for publication. The write-up contains aims, protocol, methods, and discussion on the biochemical changes, and reported symptoms.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request