ISRCTN25394628 https://doi.org/10.1186/ISRCTN25394628

The effectiveness of a fluid chart in the outpatient management of suspected dengue cases: a pilot study.

Submission date
16/12/2015

Recruitment status
No longer recruiting

Registration date
22/12/2015

Overall study status
Completed

Last Edited
20/01/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Dengue is a viral infection spread by mosquitoes. It is endemic in Malaysia, as it is in most tropical countries. Worldwide, dengue is also the fastest spreading mosquito-borne viral diseases. Symptoms can range from a mild fever to severe dengue fever with bleeding, accumulation of fluid in the lungs and abdomen, shock and death. Dengue doesn't choose who it affects, anybody can get dengue, whether young or old, woman or man. Health clinic staff and doctors would usually advise patients to drink more water if they are suspected to have dengue fever. Whether this is beneficial or not has not been well studied so far. If oral (by mouth) fluid intake is beneficial, the next question is how to improve the delivery of this advice to dengue patients who come to the primary health care clinics. A simple fluid chart has been designed that patients suspected of having dengue fever should complete every day for as long as they are being followed up by their doctor for the condition. The patient with suspected dengue fever should record on the chart when and how much he drinks every day during his illness, what types of drinks he is drinking, and whether they have needed intravenous fluid therapy. This study will look into the effects of using this fluid chart on the outcome of the patient in terms of the need for hospitalisation and the need for intravenous fluid treatment compared with patients who do not use the chart. It will also look at the effects of oral fluid intake on the haematocrit (number of red blood cells) and platelet levels in the blood for dengue patients (platelets are little pieces of blood cells important for clotting). Information regarding the haematocrit and platelet levels taken during follow up will also be collected during this study.

Who can participate?
Anyone aged at least 12 years old, has had fever for 3 days or more and is suspected to have dengue fever

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (control group) are given standard care. Those in group 2 (intervention group) are given a 24 hour fluid chart and a plastic drinking cup. Each participant in the intervention group is asked to record on the chart the amount of fluids they drink (fluid intake), what type of fluid they drink and when for the next

24 hours. They are also asked to record if they have had any intravenous fluids during that day. Participants in the control group are interviewed by the research team regarding their fluid intake over the last 24 hours (24 hour fluid recall). Blood samples are taken from all participants in order to measure haematocrit and platelet levels.

What are the possible benefits and risks of participating?
Patients may not get any direct benefits from participating in this study. However, their participation t may help doctors to know more about the effect of oral fluid intake on dengue patients, and on how to improve the advice given by the doctors and staff to patients in the future. Some of the forms to be filled in during the course of the study do need detailed information and participants are asked to answer as honestly and accurately as possible. All patient information provided will be strictly confidential.

Where is the study run from?
Primary Care Clinic, University of Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
January 2010 to July 2010

Who is funding the study?
University of Malaya (Malaysia)

Who is the main contact?
1. Dr Nazrila Hairin Nasir (scientific)
hairinnasir@gmail.com
2. Professor Chirk Jenn Ng (scientific)
ngcj@um.edu.my

Contact information

Type(s)
Scientific

Contact name
Dr Nazrila Hairin Nasir

Contact details
Klinik Kesihatan Putrajaya Presint 18
Putrajaya
Malaysia
62250
03-88810062
hairinnasir@gmail.com

Type(s)
Scientific

Contact name
Prof Chirk Jenn Ng

Contact details

Department of Primary Care
Faculty of Medicine
University of Malaya
Kuala Lumpur
Malaysia
50603
+60 14 2204 126
ngcj@um.edu.my

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluating the effectiveness of a fluid chart to improve oral fluid intake in suspected dengue patients: a feasibility study

Study objectives
This pilot randomized controlled study aimed to assess the feasibility of using a fluid chart to improve oral fluid intake in patients with suspected dengue fever in a primary care setting. We hypothesised that the usage of the fluid chart would also have some positive outcome in terms of reducing the need for intravenous fluids and hospitalisation in suspected dengue patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, University of Malaya Medical Centre, 26/05/2010, ref: 787.9

Study design
Unblinded randomized parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Dengue fever

Interventions
All patients presenting to the clinic with a history of fever for 3 days duration or more were identified by the triage counter nurses. It was standard practice that such patients would have a full blood count test done mostly before the patient's consultation with their doctors. Online results of clinical investigations were traced and those patients fulfilling the inclusion criteria were invited to participate in the study. The initial assessment of the patients and the subsequent follow-up consultations were conducted by the respective doctors working at the clinic. After the consultation, the researcher and trained research assistants obtained consent from the patient before they were randomized into either the control or intervention group. Simple randomisation was done, with a 1:1 allocation ratio, using the table of random numbers. The table of random numbers was a standard table obtained from a statistics textbook. The researchers referred directly to the table during the randomization process (no opaque envelope was used). .All the patients that were recruited into the study, regardless of randomization group, were given the standard care in the form of the patient dengue home care card. The information on this card was read out to all participants.

The control group were asked to recall their twenty four hour fluid intake, and details on what type of fluids was consumed. This information was obtained during recruitment and each follow-up.
The intervention group participants were given a plastic cup of uniform size, along with a twenty four hour fluid chart. These patients were instructed to use the cup for drinking any form of fluid they wished to consume for the duration of their participation in the study. A fluid chart was used to record the detailed fluid intake and verbal instructions were given on how to fill in the fluid chart. If a patient received intravenous fluid during the following twenty four hours either from a clinic or from the accident and emergency department treatment bay, this was recorded in the fluid chart given the time and amount of bottles received.

In addition, demographic, clinical and laboratory data were collected for all participants. All the patients recruited into the study were followed up until they had improved clinically and/or biochemically as determined by their doctors. This means that the duration of follow up varied between different participants. Data collection involved 24 hour fluid recall for the control participants, and the completed fluid charts from the intervention group. The research team would give out a new fluid chart if another appointment had been given to the participant. For both groups, the following data were recorded for each subsequent clinic follow-up: blood investigations (haemoglobin, haematocrit levels, total white cell count, platelets, and dengue serology) and temperature readings. The participants were managed by the respective doctors.

Intervention Type
Mixed

Primary outcome measure

The outcomes were assessed at the end of the two month period of data collection. The two pilot study groups were compared in terms of:
1. The hospitalization rates
2. The need for intravenous fluid treatment
During the follow up and data collection period for each participant, information regarding whether they required admission was collected, either from their medical records, or verbally from the patient during the telephone calls the research team made during defaulter tracing. Information regarding whether intravenous fluids were required for these suspected dengue patients were obtained using the fluid chart for the intervention group, and verbal interview for the control group during the participant's follow up. The feasibility of the intervention in the form of the fluid chart was assessed by its usage in the intervention group, and feedback from the intervention group participants during follow up. The feasibility of the intervention was also assessed by measuring the drop out rate of the study. The duration of data collection was for the whole duration the patient was under follow up in clinic over the 2 month period 1st June 2010 to 30th July 2010.

Secondary outcome measures
1. The severity of haemoconcentration. Four surrogate endpoints were utilized to determine this, and they were as follows:
1.1. The mean peak haematocrit
1.2. The difference in haematocrit level between the values of clinic consultation 2 – clinic consultation 1.
1.3. Those above the local cut off value of haematocrit indicative of plasma leakage.
1.4. Haematocrit fluctuation of 20% or more
2. With regards to assessing the severity of the platelet drop, two secondary endpoints were used:
2.1. The mean nadir platelet count
2.2. The difference in the platelet level between the values of clinic consultation 2 – clinic consultation1.

Data regarding the platelet and haematocrit levels were collected from the laboratory results available electronically, from the dengue home based card held by each patient, and from the medical records for each study participant. The duration of data collection was for the whole duration the patient was under follow up in clinic over the 2 month period 1st June 2010 to 30th July 2010.

Overall study start date
01/01/2010

Completion date
30/07/2010

Eligibility

Key inclusion criteria
1. Patients who are suspected to have dengue fever from the history and examination findings by a primary healthcare clinician
2. History of fever for three days or more
3. Thrombocytopenia: Platelets equal to or less than 150 x 109/l. The platelet level of 150 x 109 /L was chosen as the highest cut off point for thrombocytopenia because it is the lowest level of the normal range for platelets according to the University of Malaya Medical Centre’s clinical

laboratories. During the early febrile illness, the platelets and total white blood cell count were found to be lower among patients with dengue compared with patients with other febrile illness.
4. Age equal to or more than 12 years old. This was arbitrarily set to ensure that the patient concerned can understand instructions and fill in the fluid chart reliably and independently

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
This trial was conducted during 2 months, which was a time specified by the University during the training of my Masters in Family Medicine Programme. The aim was to recruit as many patients as possible during the 2 moth period. 143 participants were recruited, 68 participants were randomized into the control group, and 75 participants were randomised into the intervention group.

Key exclusion criteria
1. Any type of current or active malignancy
2. Human Immunodeficiency virus (HIV) or other serious underlying medical conditions conferring immunodeficiency. Immunodefiency states such as HIV or serious medical conditions were excluded from the study as febrile illnesses in these patients are usually due to complicated and multifactorial aetiologies.
3. Patients who are not given a follow-up appointment to review the clinical progression and to repeat the full blood count test. This is to ensure that the patients enrolled in this study are similar to the target population, which are patients who are suspected to have dengue fever by a primary health care provider and are being followed up for outpatient monitoring
4. Patients who are assessed on the first outpatient clinic visit and found to require hospital admission

Date of first enrolment
01/06/2010

Date of final enrolment
30/07/2010

Locations

Countries of recruitment
Malaysia

Study participating centre
Primary Care Clinic, University of Malaya Medical Centre
Lembah Pantai
Kuala Lumpur

Malaysia
59100

Sponsor information

Organisation
University of Malaya

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor type
University/education

Website
http://www.ummc.edu.my

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Publication in the Plos One Journal

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/10/2017		Yes	No
Dataset	Cummulative fluid score data 20170322. (ZIP)		20/01/2023	No	No
Dataset	Cummulative fluid score data. (XLSX)		20/01/2023	No	No
Dataset	Cummulative results output. (ZIP)		20/01/2023	No	No
Protocol file			20/01/2023	No	No