Clinical trial results:
A double blind placebo controlled randomised clinical trial to study the effect of Probiotics for the prevetion or amelioration of Antibiotic Associated Diarrhoea in residents of care homes in South Wales and England

Summary

EudraCT number	2011-006269-17
Trial protocol	GB
Global end of trial date	31 October 2013

Results information

Result version number	v1 (current)
This version publication date	29 March 2020
First version publication date	29 March 2020
Summary attachment (see zip file)	PAADII - cancelled before active statement (PAAD II Cancelled before active Statement.docx)

Trial information

Trial identification

Sponsor protocol code	SPON1069-11

Additional study identifiers

ISRCTN number	ISRCTN25324586
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cardiff University
Sponsor organisation address	Mckenzie House, Cardiff, United Kingdom,
Public contact	Julia Townson, South East Wales Trials Unit (SEWTU), Cardiff University, 44 02920687606, townson@cf.ac.uk
Scientific contact	Julia Townson, South East Wales Trials Unit (SEWTU), Cardiff University, 44 02920687606, townson@cf.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 October 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the effect of probiotics vs placebo, taken in conjunction with antibiotics, on the incidence of (AAD) in care home service users

Protection of trial subjects:

n/a

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	99999
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

One sachet (4.4g of freeze-dried powder), twice daily

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

n/a

Arms

Arm title	Probiotic

Arm description:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Arm type	Experimental
Investigational medicinal product name	VSL#3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral powder in sachet
Routes of administration	Oral use

Dosage and administration details:

One sachet (4.4g of freeze-dried powder), twice daily

Number of subjects in period 1	Probiotic
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	99999	99999	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	100		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Probiotic

Reporting group description:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Primary: at least one episode of AAD

End point title	at least one episode of AAD[1]

End point description:

99999 is "not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

End point type	Primary

End point timeframe:

n/a

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: 99999 is "not applicable" value or 0 participants, this trial was discontinued with no participants. No statistical analyses for this end point.

End point values	Probiotic			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: 1	99999			

Notes:

[2] - 99999 is "not applicable" value or 0 participants, this trial was discontinued with no participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

n/a 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: 99999 is "not applicable" value or 0 participants, this trial was discontinued with no participants. No adverse events to report.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Notes: