Clinical trial results:
The Effect of Selenium Supplementation on Musculoskeletal Health in Older Women - Double-blind, randomised, placebo-controlled trial

Summary

EudraCT number	2016-002964-15
Trial protocol	GB
Global end of trial date	30 January 2020

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022

Trial information

Trial identification

Sponsor protocol code	STH19102

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02832648
WHO universal trial number (UTN)	-
Other trial identifiers	clincal trials.gov: NCT02832648 , Funder Reference: NIHR EME 14-200-20

Notes:

Sponsors

Sponsor organisation name	Sheffield Teaching Hospitals NHS Foundation Trust
Sponsor organisation address	Trust Headquarters, 8 Beech Hill Road, Sheffield, United Kingdom, S10 2SB
Public contact	Dr Dipak Patel, Sheffield Teaching Hospitals NHS Foundation Trust, sth.ResearchAdministration@nhs.net
Scientific contact	Dr Dipak Patel, Sheffield Teaching Hospitals NHS Foundation Trust, sth.ResearchAdministration@nhs.net

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	06 November 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 November 2018
Global end of trial reached?	Yes
Global end of trial date	30 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Objective: to determine if selenium supplementation is beneficial for osteoporosis prevention and muscle function in postmenopausal women

Protection of trial subjects:

All participants were given a participant information sheet to read and consider for at least 24 hours before attending for a screening visit for the study. Participants were reviewed by a clinician who was delegated to this task, according to the strict inclusion and exclusion criteria. All participants give written informed consent prior to enrolment to the study. An assessment of radiation exposure was performed by the Radiation Protection Advisor for the Sheffield Teaching Hospitals NHS Foundation Trust prior to ethical review of the project. GCP procedures were in place to ensure appropriate consent, confidentiality and privacy. Data were handled in accordance with the Data Protection Act.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 January 2017
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: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	50
From 65 to 84 years	70

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were identified from AUBM volunteer database, Metabolic Bone Centre, Northern General Hospital, posters/email/website/word of mouth. All volunteers who passed pre-eligibility checks and attended for consent and screening were registered and allocated a study screening number.

Pre-assignment

Screening details:

Medical history for inclusion/exclusion criteria, BMD spine and hip by DXA, Blood tests –for diabetes mellitus, thyroid dysfunction, bone profile, Eligibility was confirmed by the PI or delegated medical practitioner.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Blinding implementation details:

The active treatment was overencapsulated and a matched placebo manufactured to maintain the blind.

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase 50mcg

Arm description:

Selenium 50mcg

Arm type	Experimental
Investigational medicinal product name	Selenase 50mcg
Investigational medicinal product code	
Other name	Selenium
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mcg per day for 6 months

Arm title	Selenase 200mcg

Arm description:

Selenium 200mcg

Arm type	Experimental
Investigational medicinal product name	Selenase 200mcg
Investigational medicinal product code	
Other name	Selenium
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200mcg per day for 6 months

Arm title	Placebo

Arm description:

Placebo

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo tablet once a day for 6 months

Number of subjects in period 1	Selenase 50mcg	Selenase 200mcg	Placebo
Started	40	40	40
Completed	39	39	37
Not completed	1	1	3
Consent withdrawn by subject	1	1	3

Baseline characteristics

Reporting groups	
Reporting group title	Selenase 50mcg
Reporting group description: Selenium 50mcg	
Reporting group title	Selenase 200mcg
Reporting group description: Selenium 200mcg	
Reporting group title	Placebo
Reporting group description: Placebo	

Reporting group values	Selenase 50mcg	Selenase 200mcg	Placebo
Number of subjects	40	40	40
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	66.7	64.5	66.6
standard deviation	± 6.1	± 6.1	± 6.0
Gender categorical Units: Subjects			
Female	40	40	40
Male	0	0	0

Reporting group values	Total		
Number of subjects	120		
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	120		
Male	0		

End points

End points reporting groups

Reporting group title	Selenase 50mcg
Reporting group description: Selenium 50mcg	
Reporting group title	Selenase 200mcg
Reporting group description: Selenium 200mcg	
Reporting group title	Placebo
Reporting group description: Placebo	

Primary: Between-group difference in urinary N-telopeptide of type I collagen (NTX) at 26 weeks

End point title	Between-group difference in urinary N-telopeptide of type I collagen (NTX) at 26 weeks
End point description: Between-group difference in urinary N-telopeptide of type I collagen (NTX) at 26 weeks. We chose NTX because we know how change in NTX relates to fracture risk reduction with bisphosphonates (20): a 30% decrease in NTX is associated with a 40% reduction in spine fracture and 66% of the vertebral fracture risk reduction at three years is explained by change in NTX.	
End point type	Primary
End point timeframe: 26 weeks	

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	37	34	
Units: nmol bone collagen equiv:mmol creatinine				
arithmetic mean (confidence interval 95%)	43.4 (37.4 to 50.5)	42.2 (37.5 to 47.6)	40.5 (34.9 to 47.0)	

Statistical analyses

Statistical analysis title	50 mcg vs placebo
Statistical analysis description: Primary endpoint analysis was the between-group difference in urine NTx to creatinine ratio at 26 weeks. Analysis of covariance was used with 26-week NTx to creatinine measurement as the dependent outcome variable and treatment group and baseline NTx to creatinine measurement as the independent variables. If the residuals from the model were not normally distributed, the values would be log transformed and the treatment group differences back transformed to be presented as a ratio.	
Comparison groups	Placebo v Selenase 50mcg

Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.74 [1]
Method	ANCOVA
Parameter estimate	ratio of means
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.19

Notes:

[1] - no significant difference across the three arms

Statistical analysis title	200 mcg vs placebo

Statistical analysis description:

Primary endpoint analysis was the between-group difference in urine NTx to creatinine ratio at 26 weeks.
Analysis of covariance was used with 26-week NTx to creatinine measurement as the dependent outcome variable and treatment group and baseline NTx to creatinine measurement as the independent variables. If the residuals from the model were not normally distributed, the values would be log transformed and the treatment group differences back transformed to be presented as a ratio.

Comparison groups	Selenase 200mcg v Placebo
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.66
Method	ANCOVA
Parameter estimate	ratio of means
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.12

Statistical analysis title	200 mcg vs 50 mcg

Statistical analysis description:

Primary endpoint analysis was the between-group difference in urine NTx to creatinine ratio at 26 weeks.
Analysis of covariance was used with 26-week NTx to creatinine measurement as the dependent outcome variable and treatment group and baseline NTx to creatinine measurement as the independent variables. If the residuals from the model were not normally distributed, the values would be log transformed and the treatment group differences back transformed to be presented as a ratio.

Comparison groups	Selenase 50mcg v Selenase 200mcg

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.43
Method	ANCOVA
Parameter estimate	ratio of means
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.09

Secondary: serum selenium

End point title	serum selenium

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	39	33	
Units: mcg/l				
arithmetic mean (confidence interval 95%)	96.2 (90.7 to 101.6)	105.7 (99.5 to 111.9)	77.7 (73.3 to 82.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: serum selenoprotein P

End point title	serum selenoprotein P

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	39	33	
Units: mg/l				
arithmetic mean (confidence interval 95%)	6.25 (5.79 to 6.7)	6.03 (5.54 to 6.51)	5.31 (4.75 to 5.87)	

Statistical analyses

No statistical analyses for this end point

Secondary: serum procollagen type I N propeptide (PINP)

End point title	serum procollagen type I N propeptide (PINP)

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	34	
Units: mcg/l				
geometric mean (confidence interval 95%)	46.8 (41 to 53.3)	47.0 (41.3 to 53.6)	47 (42.5 to 52)	

Statistical analyses

No statistical analyses for this end point

Secondary: serum osteocalcin

End point title	serum osteocalcin

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	34	
Units: mcg/l				
geometric mean (confidence interval 95%)	14.1 (12.3 to 16.2)	13.9 (12.4 to 15.6)	14.4 (12.6 to 16.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: serum C–terminal cross-linking telopeptide of type I collagen (CTX)

End point title	serum C–terminal cross-linking telopeptide of type I collagen (CTX)

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	34	
Units: mcg/l				
geometric mean (confidence interval 95%)	0.12 (0.09 to 0.16)	0.11 (0.09 to 0.15)	0.13 (0.09 to 0.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: total hip bone mineral density by DXA

End point title	total hip bone mineral density by DXA

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	39	34	
Units: g/cmsq				
arithmetic mean (confidence interval 95%)	-1.2 (-1.4 to -1.0)	-0.9 (-1.1 to -0.7)	-1.2 (-1.5 to -1.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: lumbar spine bone mineral density by DXA

End point title	lumbar spine bone mineral density by DXA

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	34	
Units: g/cmsq				
arithmetic mean (confidence interval 95%)	-1.8 (-2.1 to -1.5)	-1.9 (-2.1 to -1.7)	-1.8 (-2.1 to -1.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: short physical performance battery

End point title	short physical performance battery

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	39	36	
Units: score /12				
number (confidence interval 95%)	10.4 (9.9 to 10.9)	10.3 (9.7 to 10.8)	10.9 (10.5 to 11.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: grip strength dominant hand

End point title	grip strength dominant hand

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	39	36	
Units: kg				
arithmetic mean (confidence interval 95%)	18.9 (17.4 to 20.4)	18.4 (16.9 to 19.8)	18.1 (16.6 to 19.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: glutathione peroxidase activity

End point title	glutathione peroxidase activity

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	39	33	
Units: IU/l				
arithmetic mean (confidence interval 95%)	176.8 (149.2 to 204.3)	160.1 (132.4 to 187.8)	175.4 (147.5 to 203.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: serum highly sensitive c-reactive protein

End point title	serum highly sensitive c-reactive protein

End point description:

End point type	Secondary

End point timeframe:

26 weeks

End point values	Selenase 50mcg	Selenase 200mcg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	37	35	
Units: mg/l				
geometric mean (confidence interval 95%)	0.81 (0.58 to 1.13)	1.09 (0.74 to 1.60)	1.31 (0.88 to 1.94)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The reporting period for adverse events was from the date of informed consent until 28 days after the last administration of IMP.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	All enrolled

Reporting group description: -

Serious adverse events	All enrolled		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 120 (2.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon Cancer			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangiocarcinoma			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Left Deep Vein Thrombosis			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac ischaemia			

subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All enrolled		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	80 / 120 (66.67%)		
Surgical and medical procedures			
Removal of wisdom teeth			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Foot surgery			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Joint replacement (excl hip and knee)			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
General disorders and administration site conditions			
Swelling of legs			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	2		
Chest pain			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Sinus pain			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	3		

Cough subjects affected / exposed occurrences (all)	5 / 120 (4.17%) 5		
Sore throat subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
COPD exacerbation subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Asthmatic attack subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Psychiatric disorders Low mood subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Investigations Raised blood pressure subjects affected / exposed occurrences (all)	2 / 120 (1.67%) 2		
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	5 / 120 (4.17%) 6		
Baker's cyst ruptured subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Laceration of leg subjects affected / exposed occurrences (all)	2 / 120 (1.67%) 2		
Whiplash injury subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Pulled muscle subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		

Insect bite subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Bee sting subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Fracture rib1 subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Sprained ankle subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Cardiac disorders Angina subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Headache subjects affected / exposed occurrences (all)	2 / 120 (1.67%) 2		
Taste metallic subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Trapped nerve subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Migraine subjects affected / exposed occurrences (all)	2 / 120 (1.67%) 2		
Syncope vasovagal subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Eye disorders			
Eye floaters			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Gastrointestinal disorders			
nausea			
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	3		
Stomachache			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	4		
Dry mouth			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Saliva secretion excessive			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Mouth ulcer			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Gastroesophageal reflux			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Rectal polyp			

subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Discolouration nail			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Blister of hip, thigh, leg, and ankle, without mention of infection			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Hair thinning			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Splitting nails			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Hives			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Renal and urinary disorders			
Urgency urination			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Urination frequency of			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
kidney stone			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Renal artery aneurysm			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Aching joints			
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	3		
Trigger thumb			

subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Plantar fasciitis			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Jaw pain			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Swelling of elbows			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Back muscle spasms			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Pain in (r) shoulder			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Leg pain			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Knee pain			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Pain in thumb			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Pain foot			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Infections and infestations			
Cystitis			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Cold			
subjects affected / exposed	15 / 120 (12.50%)		
occurrences (all)	18		

Urinary tract infection			
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	3		
Ear infection			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Gastroenteritis			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Throat infection			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Chest infection			
subjects affected / exposed	3 / 120 (2.50%)		
occurrences (all)	3		
Shingles			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Knee pain			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Streptococcus pneumoniae pneumonia			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		

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.

Intended to measure hydroperoxidases as a marker of reactive oxygen species but assay was withdrawn.Most IL6 measurements were below the limit of detection of 1.6ng/l (74/110 at base, 71/110 at w13 and 74/108 at w26), no further analysis conducted.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33842907