Clinical trial results:
The effects of COX-inhibiting drugs on skeletal muscle adaptations to resistance exercise in healthy adults.

Summary

EudraCT number	2014-004872-47
Trial protocol	SE
Global end of trial date	10 June 2016

Results information

Result version number	v1 (current)
This version publication date	04 April 2021
First version publication date	04 April 2021
Summary attachment (see zip file)	Lilja et al. Acta Physiol (Lilja_et_al-2017-Acta_Physiologica.pdf)

Trial information

Trial identification

Sponsor protocol code	NSAID2015

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02531451
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Karolinska Institutet
Sponsor organisation address	17177, Stockholm, Sweden,
Public contact	Tommy Lundberg, Karolinska Institutet, Lab Medicine Dept, Clinical Physiology C1:82,Karolinska Univ Hosp, Huddinge, +46 858586771, tommy.lundberg@ki.se
Scientific contact	Tommy Lundberg, Karolinska Institutet, Lab Medicine Dept, Clinical Physiology C1:82,Karolinska Univ Hosp, Huddinge, +46 858586771, tommy.lundberg@ki.se

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	01 September 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 June 2016
Global end of trial reached?	Yes
Global end of trial date	10 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the effects of Ibuprofen on skeletal muscle adaptations to resistance exercise (see study protocol).

Protection of trial subjects:

Drug accountability, chief medical physician involvement, immediate reporting of adverse effects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	31
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from the Stockholm region between September 2015 to June 2016.

Pre-assignment

Screening details:

Recreationally active men and women aged 18–35 years were screened. From the 48 individuals who were assessed for eligibility, 31 were included in the final data analysis.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	Acetylsalicylic acid

Arm description:

The control group received acetylsalicylic acid one dose per day (75 mg) in conjunction with their morning meal. One leg was assigned to perform training with maximal volitional work allowed in each repetition using a flywheel ergometer, while on the other leg the training volume was matched between groups using regular weight-stack training.

Arm type	Active comparator
Investigational medicinal product name	Acetylsalicylic acid
Investigational medicinal product code	SUB12730MIG
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Acetylsalicylic acid was instructed to take one dose per day (75 mg) in conjunction with their morning meal.

Arm title	Ibuprofen

Arm description:

The ibuprofen group was instructed to take three doses/day (~08:00, ~14:00 and ~20:00 h.) corresponding to the maximal over-the counter daily dose of 1200 mg (400 mg dose-1). One leg was assigned to perform training with maximal volitional work allowed in each repetition using a flywheel ergometer, while on the other leg the training volume was matched between groups using regular weight-stack training.

Arm type	Experimental
Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	SUB08098MIG
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

The ibuprofen group was instructed, orally and in writing, to take three doses/day (~08:00, ~14:00 and ~20:00 h.) corresponding to the maximal over-thec ounter daily dose of 1200 mg (400 mg dose-1).

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: The subjects were not blind to their treatment. The research personnel responsible for monitoring training sessions stayed blind for the drug assignment during the whole intervention, and the

individual who performed the analysis was blind.

Number of subjects in period 1	Acetylsalicylic acid	Ibuprofen
Started	16	15
Completed	16	15

Baseline characteristics

Reporting groups	
Reporting group title	Acetylsalicylic acid
Reporting group description:	
The control group received acetylsalicylic acid one dose per day (75 mg) in conjunction with their morning meal. One leg was assigned to perform training with maximal volitional work allowed in each repetition using a flywheel ergometer, while on the other leg the training volume was matched between groups using regular weight-stack training.	
Reporting group title	Ibuprofen
Reporting group description:	
The ibuprofen group was instructed to take three doses/day (~08:00, ~14:00 and ~20:00 h.) corresponding to the maximal over-the counter daily dose of 1200 mg (400 mg dose-1). One leg was assigned to perform training with maximal volitional work allowed in each repetition using a flywheel ergometer, while on the other leg the training volume was matched between groups using regular weight-stack training.	

Reporting group values	Acetylsalicylic acid	Ibuprofen	Total
Number of subjects	16	15	31
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	15	31
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	26	27	
standard deviation	± 4	± 5	-
Gender categorical Units: Subjects			
Female	8	6	14
Male	8	9	17
Height Units: Cm			
arithmetic mean	174	171	
standard deviation	± 13	± 9	-
Body mass Units: Kg			
arithmetic mean	79	77	
standard deviation	± 22	± 15	-
m. Quadriceps volume Merged Units: (cm3)			
arithmetic mean	1026	952	

standard deviation	± 430	± 272	-
m. quadriceps volume WS leg			
WS = Weight stack training			
Units: cm3			
arithmetic mean	1011	939	
standard deviation	± 413	± 258	-
m. quadriceps volume FW leg			
FW = Flywheel ergometer			
Units: cm3			
arithmetic mean	1041	964	
standard deviation	± 449	± 290	-
m. quadriceps mean CSA Merged			
CSA = Muscle volume, mean cross-sectional area			
Units: cm2			
arithmetic mean	69	71	
standard deviation	± 22	± 15	-
m. quadriceps mean CSA WS leg			
CSA = Muscle volume, mean cross-sectional area. WS = Weight stack training.			
Units: cm2			
arithmetic mean	69	71	
standard deviation	± 21	± 15	-
m. quadriceps mean CSA FW leg			
CSA = Muscle volume, mean cross-sectional area. FW = Flywheel ergometer.			
Units: cm2			
arithmetic mean	70	71	
standard deviation	± 22	± 16	-
m. quadriceps signal intensity Merged			
MGV = Mean grey value.			
Units: MGV			
arithmetic mean	32.2	33.5	
standard deviation	± 7.1	± 9.8	-
m. quadriceps signal intensity WS leg			
WS = Weight stack training. MGV = Mean grey value.			
Units: MGV			
arithmetic mean	31.9	32.4	
standard deviation	± 7.9	± 9.2	-
m. quadriceps signal intensity FW leg			
FW = Flywheel ergometer. MGV = Mean grey value.			
Units: MGV			
arithmetic mean	32.6	34.5	
standard deviation	± 8.1	± 11.2	-
m. biceps femoris mean CSA Merged			
CSA = Muscle volume, mean cross-sectional area.			
Units: cm2			
arithmetic mean	12.5	12.7	
standard deviation	± 2.6	± 2.5	-
m. biceps femoris mean CSA WS leg			
CSA = Muscle volume, mean cross-sectional area. WS = Weight stack training			
Units: cm2			
arithmetic mean	12.6	12.4	
standard deviation	± 2.8	± 2.5	-
m. biceps femoris mean CSA FW leg			

CSA = Muscle volume, mean cross-sectional area. FW = Flywheel ergometer.			
Units: cm2			
arithmetic mean	12.3	13.1	
standard deviation	± 2.6	± 2.9	-
Estimated muscle water content			
Units: Percent			
arithmetic mean	74.8	75.5	
standard deviation	± 1.3	± 1.5	-
Protein concentration			
Units: ug mg-1 dry weight			
arithmetic mean	317	307	
standard deviation	± 111	± 78	-
Training-specific strength WS leg			
WS = Weight stack training.			
Units: Kg			
arithmetic mean	18.7	18.7	
standard deviation	± 8.4	± 6.2	-
Training-specific strength FW leg			
Units: Average peak power			
arithmetic mean	126	124	
standard deviation	± 54	± 50	-

End points

End points reporting groups

Reporting group title	Acetylsalicylic acid

Reporting group description:

The control group received acetylsalicylic acid one dose per day (75 mg) in conjunction with their morning meal. One leg was assigned to perform training with maximal volitional work allowed in each repetition using a flywheel ergometer, while on the other leg the training volume was matched between groups using regular weight-stack training.

Reporting group title	Ibuprofen

Reporting group description:

The ibuprofen group was instructed to take three doses/day (~08:00, ~14:00 and ~20:00 h.) corresponding to the maximal over-the counter daily dose of 1200 mg (400 mg dose-1). One leg was assigned to perform training with maximal volitional work allowed in each repetition using a flywheel ergometer, while on the other leg the training volume was matched between groups using regular weight-stack training.

Primary: Difference in Quadriceps volume Merged

End point title	Difference in Quadriceps volume Merged

End point description:

Difference in Quadriceps volume Merged from baseline to 8 weeks post resistance training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	7.5	3.7		

Statistical analyses

Statistical analysis title	Difference in Quadriceps volume Merged

Statistical analysis description:

Difference in Quadriceps volume Merged from pre- to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.05
Method	ANOVA

Notes:

[1] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).
Group 9 time interaction (P < 0.05).

Primary: Difference in quadriceps volume WS leg

End point title	Difference in quadriceps volume WS leg

End point description:

Difference in quadriceps volume WS leg from baseline to 8 weeks post resistance training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	8.1	4.7		

Statistical analyses

Statistical analysis title	Difference in quadriceps volume WS leg

Statistical analysis description:

Difference in quadriceps volume WS leg from pre- to 8 weeks post training.

Comparison groups	Ibuprofen v Acetylsalicylic acid
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	< 0.05
Method	ANOVA

Notes:

[2] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).
Group 9 time interaction (P < 0.05).

Primary: Difference in quadriceps volume FW leg

End point title	Difference in quadriceps volume FW leg

End point description:

Difference in quadriceps volume FW leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	6.9	2.7		

Statistical analyses

Statistical analysis title	Difference in quadriceps volume FW leg

Statistical analysis description:

Difference in quadriceps volume FW leg from pre- to 8 weeks post training.

Comparison groups	Ibuprofen v Acetylsalicylic acid
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	< 0.05
Method	ANOVA

Notes:

[3] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).
Group 9 time interaction (P < 0.05).

Primary: Difference in quadriceps mean CSA Merged

End point title	Difference in quadriceps mean CSA Merged

End point description:

Difference in quadriceps mean CSA Merged from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	7.5	3.7		

Statistical analyses

Statistical analysis title	Difference in quadriceps mean CSA Merged

Statistical analysis description:

Difference in quadriceps mean CSA Merged from pre- to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	< 0.05
Method	ANOVA

Notes:

[4] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).
Group 9 time interaction (P < 0.05).

Primary: Difference in quadriceps mean CSA WS leg

End point title	Difference in quadriceps mean CSA WS leg

End point description:

Difference in quadriceps mean CSA WS leg from baseline to 8 weeks post resistance training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	8.0	4.7		

Statistical analyses

Statistical analysis title	Difference in quadriceps mean CSA WS leg

Statistical analysis description:

Difference in quadriceps mean CSA WS leg from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	< 0.05
Method	ANOVA

Notes:

[5] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).
Group 9 time interaction (P < 0.05).

Primary: Difference in quadriceps mean CSA FW leg

End point title	Difference in quadriceps mean CSA FW leg

End point description:

Difference in quadriceps mean CSA FW leg from baseline to 8 weeks post resistance training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	6.9	3.1		

Statistical analyses

Statistical analysis title	Difference in quadriceps mean CSA FW leg

Statistical analysis description:

Difference in quadriceps mean CSA FW leg from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	< 0.05
Method	ANOVA

Notes:

[6] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time ($P < 0.05$).
Group 9 time interaction ($P < 0.05$).

Primary: Difference in quadriceps signal intensity Merged

End point title	Difference in quadriceps signal intensity Merged

End point description:

Difference in quadriceps signal intensity Merged from baseline to 8 weeks post resistance training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	1.9	0.9		

Statistical analyses

Statistical analysis title	Difference quadriceps signal intensity Merged

Statistical analysis description:

Difference quadriceps signal intensity Merged from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	> 0.05
Method	ANOVA

Notes:

[7] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in quadriceps signal intensity WS leg

End point title	Difference in quadriceps signal intensity WS leg

End point description:

Difference in quadriceps signal intensity WS leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	1.9	1.6		

Statistical analyses

Statistical analysis title	Difference in quadriceps signal intensity WS leg

Statistical analysis description:

Difference in quadriceps signal intensity WS leg from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	> 0.05
Method	ANOVA

Notes:

[8] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in quadriceps signal intensity FW leg

End point title	Difference in quadriceps signal intensity FW leg

End point description:

Difference in quadriceps signal intensity FW leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	-4.1	0.4		

Statistical analyses

Statistical analysis title	Difference in quadriceps signal intensity FW leg

Statistical analysis description:

Difference in quadriceps signal intensity FW leg from baseline to 8 weeks post training.

Comparison groups	Ibuprofen v Acetylsalicylic acid
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	> 0.05
Method	ANOVA

Notes:

[9] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in biceps femoris mean CSA Merged

End point title	Difference in biceps femoris mean CSA Merged

End point description:

Difference in biceps femoris mean CSA Merged from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	-0.1	-1.0		

Statistical analyses

Statistical analysis title	Difference in biceps femoris mean CSA Merged

Statistical analysis description:

Difference in biceps femoris mean CSA Merged from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	> 0.05
Method	ANOVA

Notes:

[10] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in biceps femoris mean CSA WS leg

End point title	Difference in biceps femoris mean CSA WS leg

End point description:

Difference in biceps femoris mean CSA WS leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	-0.2	-1.0		

Statistical analyses

Statistical analysis title	Difference in biceps femoris mean CSA WS leg

Statistical analysis description:

Difference in biceps femoris mean CSA WS leg from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	> 0.05
Method	ANOVA

Notes:

[11] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in biceps femoris mean CSA FW leg

End point title	Difference in biceps femoris mean CSA FW leg

End point description:

Difference in biceps femoris mean CSA FW leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	0.1	-1.2		

Statistical analyses

Statistical analysis title	Difference in biceps femoris mean CSA FW leg

Statistical analysis description:

Difference in biceps femoris mean CSA FW leg from baseline to 8 weeks post training.

Comparison groups	Ibuprofen v Acetylsalicylic acid
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	> 0.05
Method	ANOVA

Notes:

[12] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in Estimated muscle water content

End point title	Difference in Estimated muscle water content

End point description:

Difference in Estimated muscle water content from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	0.6	0.0		

Statistical analyses

Statistical analysis title	Difference in Estimated muscle water content

Statistical analysis description:

Difference in Estimated muscle water content from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	> 0.05
Method	ANOVA

Notes:

[13] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in Protein concentration

End point title	Difference in Protein concentration

End point description:

Difference in Protein concentration from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	11	11		

Statistical analyses

Statistical analysis title	Difference in Protein concentration

Statistical analysis description:

Difference in Protein concentration from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	> 0.05
Method	ANOVA

Notes:

[14] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.

Primary: Difference in Training-specific strength WS leg

End point title	Difference in Training-specific strength WS leg

End point description:

Difference in Training-specific strength WS leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	26	26		

Statistical analyses

Statistical analysis title	Difference in Training-specific strength WS leg

Statistical analysis description:

Difference in Training-specific strength WS leg from baseline to 8 weeks post training.

Comparison groups	Ibuprofen v Acetylsalicylic acid

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	< 0.05
Method	ANOVA

Notes:

[15] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).

Primary: Difference in Training-specific strength FW leg

End point title	Difference in Training-specific strength FW leg

End point description:

Difference in Training-specific strength FW leg from baseline to 8 weeks post training.

End point type	Primary

End point timeframe:

Baseline to 8 weeks post resistance training.

End point values	Acetylsalicylic acid	Ibuprofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Percent				
number (not applicable)	29	20		

Statistical analyses

Statistical analysis title	Difference in Training-specific strength FW leg

Statistical analysis description:

Difference in Training-specific strength FW leg from baseline to 8 weeks post training.

Comparison groups	Acetylsalicylic acid v Ibuprofen
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority[16]
P-value	< 0.05
Method	ANOVA

Notes:

[16] - Two-way ANOVAs with factors group (ASA vs. IBU) and time (PRE vs. POST) were used to compare training-induced changes in all dependent variables across the two groups.
Main effect of time (P < 0.05).
Group 9 time interaction (P < 0.05).

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Baseline and up to 8 weeks.	
Assessment type	Systematic
Dictionary used	
Dictionary name	Adverse events NSAID
Dictionary version	n/a
Reporting groups	
Reporting group title	Acetylsalicylic acid
Reporting group description: -	
Reporting group title	Ibuprofen
Reporting group description: -	

Serious adverse events	Acetylsalicylic acid	Ibuprofen	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Acetylsalicylic acid	Ibuprofen	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 16 (56.25%)	6 / 15 (40.00%)	
Gastrointestinal disorders			
Abdominal pain, heartburn	Additional description: In total 15 adverse events. 4 were classified as moderate (1 IBU, 3 ASA), and 11 were classified as mild in severity (5 IBU, 6 ASA). 5 of the events (abdominal pain 3, heartburn 2) were possibly or likely related to the study drug (IBU 3, ASA 2).		
subjects affected / exposed	9 / 16 (56.25%)	6 / 15 (40.00%)	
occurrences (all)	9	6	

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.

A limitation of the current study was that we did not include a non-treated control group.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28834248