A Clinical Trial of CSL's 2010/2011 Formulation of Enzira® in a Healthy Adult Population

This study has been completed.

Sponsor:
CSL Limited

Information provided by (Responsible Party):
CSL Limited

ClinicalTrials.gov Identifier:
NCT01113580

First received: April 26, 2010
Last updated: June 13, 2012
Last verified: June 2012
History of Changes

Results First Received: June 13, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
Condition:	Influenza
Intervention:	Biological: CSL's 2010/2011 Formulation of Enzira® Vaccine

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Participant Flow: Overall Study

	Adults	Older Adults
STARTED	60	60
COMPLETED	59	60
NOT COMPLETED	1	0
Protocol Violation	1	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older
Total	Total of all reporting groups

Baseline Measures

	Adults	Older Adults	Total
Number of Participants [units: participants]	60	60	120
Age, Customized [units: participants]			
< 18 years	0	0	0
18 to 59 years	60	0	60
>= 60 years	0	60	60
Gender [units: participants]			
Female	29	24	53
Male	31	36	67

Outcome Measures

Hide All Outcome Measures

1. Primary: The Percentage of Evaluable Participants Achieving Seroconversion or Significant Increase in Antibody Titre. [Time Frame: Approximately 21 days after vaccination]

Measure Type	Primary

Measure Title	The Percentage of Evaluable Participants Achieving Seroconversion or Significant Increase in Antibody Titre.
Measure Description	As per the criteria specified in the CPMP/BWP/214/96 Note for Guidance on Harmonisation of Requirements for Influenza Vaccines. For haemagglutination inhibition (HI), seroconversion is defined as achieving a post-vaccination titre of ≥ 40 for those participants with a pre-vaccination HI titre of < 10; significant increase is defined as a four-fold or greater increase in HI titre for those participants with a pre-vaccination HI titre of ≥ 10.
Time Frame	Approximately 21 days after vaccination
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Evaluable Population comprised all participants who were vaccinated with the study vaccine, provided both pre- and post-vaccination antibody titre results, and were not excluded from the analyses (eg, for the use of a prohibited medication or a laboratory-confirmed influenza virus infection between Visits 1 and 2).

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Measured Values

	Adults	**Older Adults**
Number of Participants Analyzed [units: participants]	**58**	**60**
The Percentage of Evaluable Participants Achieving Seroconversion or Significant Increase in Antibody Titre. [units: Percentage of participants] Number (95% Confidence Interval)		
A/California/7/2009 (H1N1)-like strain	**89.7 (78.8 to 96.1)**	**80.0 (67.7 to 89.2)**
A/Perth/16/2009 (H3N2)-like strain	**89.7 (78.8 to 96.1)**	**71.7 (58.6 to 82.5)**
B/Brisbane/60/2008-like strain	**63.8 (50.1 to 76.0)**	**28.3 (17.5 to 41.4)**

No statistical analysis provided for The Percentage of Evaluable Participants Achieving Seroconversion or Significant Increase in Antibody Titre.

2. Primary: The Geometric Mean Fold Increase (GMFI) in Antibody Titre After Vaccination. [Time Frame: Approximately 21 days after vaccination]

Measure Type	Primary
Measure Title	The Geometric Mean Fold Increase (GMFI) in Antibody Titre After Vaccination.
Measure Description	GMFI is defined as the geometric mean of the fold increases of post-vaccination antibody titre over the pre-vaccination antibody titre.

Time Frame	Approximately 21 days after vaccination
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Evaluable Population comprised all participants who were vaccinated with the study vaccine, provided both pre- and post-vaccination antibody titre results, and were not excluded from the analyses (eg, for the use of a prohibited medication or a laboratory-confirmed influenza virus infection between Visits 1 and 2).

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Measured Values

	Adults	**Older Adults**
Number of Participants Analyzed [units: participants]	**58**	**60**
The Geometric Mean Fold Increase (GMFI) in Antibody Titre After Vaccination. [units: Fold increase] Number (95% Confidence Interval)		
A/California/7/2009 (H1N1)-like strain	**20.48 (14.714 to 28.512)**	**12.90 (8.218 to 20.239)**
A/Perth/16/2009 (H3N2)-like strain	**24.70 (16.967 to 35.958)**	**11.53 (7.313 to 18.191)**
B/Brisbane/60/2008-like strain	**6.63 (4.598 to 9.571)**	**2.77 (2.055 to 3.747)**

No statistical analysis provided for The Geometric Mean Fold Increase (GMFI) in Antibody Titre After Vaccination.

3. Primary: The Percentage of Evaluable Participants Achieving a HI Titre ≥ 40 or Single Radial Haemolysis (SRH) Area ≥ 25 mm2. [Time Frame: Approximately 21 days after vaccination]

Measure Type	Primary
Measure Title	The Percentage of Evaluable Participants Achieving a HI Titre ≥ 40 or Single Radial Haemolysis (SRH) Area ≥ 25 mm2.
Measure Description	No text entered.
Time Frame	Approximately 21 days after vaccination
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Evaluable Population comprised all participants who were vaccinated with the study vaccine, provided both pre- and post-vaccination

antibody titre results, and were not excluded from the analyses (eg, for the use of a prohibited medication or a laboratory-confirmed influenza virus infection between Visits 1 and 2).

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Measured Values

	Adults	Older Adults
Number of Participants Analyzed [units: participants]	**58**	**60**
The Percentage of Evaluable Participants Achieving a HI Titre ≥ 40 or Single Radial Haemolysis (SRH) Area ≥ 25 mm2. [units: Percentage of participants] Number (95% Confidence Interval)		
A/California/7/2009 (H1N1)-like strain	**91.4 (81.0 to 97.1)**	**90.0 (79.5 to 96.2)**
A/Perth/16/2009 (H3N2)-like strain	**98.3 (90.8 to 100.0)**	**96.7 (88.5 to 99.6)**
B/Brisbane/60/2008-like strain	**89.7 (78.8 to 96.1)**	**70.0 (56.8 to 81.2)**

No statistical analysis provided for The Percentage of Evaluable Participants Achieving a HI Titre ≥ 40 or Single Radial Haemolysis (SRH) Area ≥ 25 mm2.

4. Secondary: Frequency of Any Solicited Adverse Events (AEs) [Time Frame: During the 4 days after vaccination (Day 0 plus 3 days)]

Measure Type	Secondary
Measure Title	Frequency of Any Solicited Adverse Events (AEs)
Measure Description	The number of participants reporting any solicited AEs.
Time Frame	During the 4 days after vaccination (Day 0 plus 3 days)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Safety Population comprised all participants who received study vaccine and provided follow-up safety data.

Reporting Groups

	Description

Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Measured Values

	Adults	Older Adults
Number of Participants Analyzed [units: participants]	**60**	**60**
Frequency of Any Solicited Adverse Events (AEs) [units: participants]		
Any local solicited AE	**32**	**18**
Any induration larger than 50 mm	**2**	**0**
Any erythema	**22**	**9**
Any ecchymosis	**5**	**4**
Any pain	**22**	**10**
Any general (systemic) solicited AE	**4**	**3**
Any temperature above 38 degrees C for ≥ 24 hours	**0**	**3**
Any chills	**4**	**2**
Any malaise	**3**	**2**

No statistical analysis provided for Frequency of Any Solicited Adverse Events (AEs)

5. Secondary: Frequency and Intensity of Any Unsolicited Adverse Events [Time Frame: After vaccination until the end of the study; approximately 21 days]

Measure Type	Secondary
Measure Title	Frequency and Intensity of Any Unsolicited Adverse Events
Measure Description	Unsolicited adverse event (UAE) grading: Mild: Symptoms were easily tolerated and there was no interference with daily activities. Moderate: Enough discomfort to have caused some interference with daily activities. Severe: Symptoms that prevented normal, everyday activities.
Time Frame	After vaccination until the end of the study; approximately 21 days
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Safety Population comprised all participants who received study vaccine and provided follow-up safety data.

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Measured Values

	Adults	Older Adults
Number of Participants Analyzed [units: participants]	60	60
Frequency and Intensity of Any Unsolicited Adverse Events [units: participants]		
Number of participants with at least one UAE	28	22
Number of participants reporting mild UAE	22	19
Number of participants reporting moderate UAE	7	2
Number of participants reporting severe UAE	3	2

No statistical analysis provided for Frequency and Intensity of Any Unsolicited Adverse Events

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Approximately 21 days after study vaccination for serious adverse events and unsolicited adverse events.
Additional Description	Other adverse events presented were unsolicited adverse events up to approximately 21 days after study vaccination.

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Serious Adverse Events

	Adults	Older Adults
Total, serious adverse events		
# participants affected / at risk	**0/60 (0.00%)**	**0/60 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Approximately 21 days after study vaccination for serious adverse events and unsolicited adverse events.
Additional Description	Other adverse events presented were unsolicited adverse events up to approximately 21 days after study vaccination.

Frequency Threshold

Threshold above which other adverse events are reported	2.0%

Reporting Groups

	Description
Adults	Healthy volunteers aged 18 to 59 years
Older Adults	Healthy volunteers aged 60 years or older

Other Adverse Events

	Adults	Older Adults
Total, other (not including serious) adverse events		
# participants affected / at risk	**22/60 (36.67%)**	**15/60 (25.00%)**
Gastrointestinal disorders		
Toothache † 1		
# participants affected / at risk	**2/60 (3.33%)**	**0/60 (0.00%)**
# events	**2**	**0**
General disorders		
Influenza like illness † 1		
# participants affected / at risk	**3/60 (5.00%)**	**2/60 (3.33%)**
# events	**3**	**2**
Vaccination site erythema † 1		
# participants affected / at risk	**2/60 (3.33%)**	**1/60 (1.67%)**
# events	**2**	**1**
Vaccination site induration † 1		
# participants affected / at risk	**2/60 (3.33%)**	**0/60 (0.00%)**
# events	**2**	**0**
Infections and infestations		
Upper respiratory tract infection † 1		
# participants affected / at risk	**3/60 (5.00%)**	**5/60 (8.33%)**
# events	**3**	**5**
Rhinitis † 1		
# participants affected / at risk	**2/60 (3.33%)**	**2/60 (3.33%)**
# events	**2**	**2**
Gastroenteritis † 1		
# participants affected / at risk	**2/60 (3.33%)**	**1/60 (1.67%)**
# events	**2**	**1**
Musculoskeletal and connective tissue disorders		
Myalgia † 1		
# participants affected / at risk	**2/60 (3.33%)**	**0/60 (0.00%)**
# events	**2**	**0**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**12/60 (20.00%)**	**4/60 (6.67%)**
# events	**12**	**4**
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain † 1		
# participants affected / at risk	**2/60 (3.33%)**	**1/60 (1.67%)**

# events	2	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: CSL agreements and restrictions on publishing may vary with individual investigators; however, CSL will not prohibit any investigator from publishing. CSL supports the publication of results from all centers of a multi-center trial and generally requires that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Clinical Trial Disclosure Manager
Organization: CSL Limited
phone: Use email contact
e-mail: csl.clinicaltrials@csl.com.au

No publications provided

Responsible Party:	CSL Limited
ClinicalTrials.gov Identifier:	NCT01113580 History of Changes
Other Study ID Numbers:	CSLCT-**ASU-10-66** 2010-019532-12 (EudraCT Number)
Study First Received:	April 26, 2010
Results First Received:	June 13, 2012
Last Updated:	June 13, 2012
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency

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