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Trial record **2 of 2** for: 09-57

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A Study to Assess the Immunogenicity and Safety of CSL's 2009 / 2010 Formulation of Enzira® Vaccine in Healthy Volunteers

This study has been completed.

Sponsor:
CSL Limited

Information provided by (Responsible Party):
CSL Limited

ClinicalTrials.gov Identifier:
NCT00888381

First received: April 24, 2009
Last updated: March 27, 2015
Last verified: March 2015
History of Changes

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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: Inactivated Influenza Vaccine (2009 / 2010 formulation)

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	**60**	**59**
NOT COMPLETED	**0**	**1**
Lost to Follow-up	**0**	**1**

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 [units: years] Mean (Standard Deviation)	**35.3 (12.31)**	**66.2 (5.92)**	**50.7 (18.24)**
Gender [units: participants]			
Female	**27**	**29**	**56**
Male	**33**	**31**	**64**

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]	**60**	**58**
The Percentage of Evaluable Participants Achieving Seroconversion or Significant Increase in Antibody Titre. [units: percentage of participants] Number (95% Confidence Interval)		
A/Brisbane/59/2007 (H1N1) - like strain	**91.7 (81.6 to 97.2)**	**53.4 (39.9 to 66.7)**
A/Brisbane/10/2007 (H3N2) - like strain	**93.3 (83.8 to 98.2)**	**63.8 (50.1 to 76.0)**
B/Brisbane/60/2008 - like strain	**76.7 (64.0 to 86.6)**	**46.6 (33.3 to 60.1)**

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]	**60**	**58**
The Geometric Mean Fold Increase (GMFI) in Antibody Titre After Vaccination. [units: percentage of participants] Number (95% Confidence Interval)		
A/Brisbane/59/2007 (H1N1) - like strain	**27.86 (19.339 to 40.129)**	**5.02 (3.575 to 7.048)**
A/Brisbane/10/2007(H3N2) - like strain	**30.32 (21.003 to 43.772)**	**9.80 (6.105 to 15.738)**
B/Brisbane/60/2008 - like strain	**12.85 (9.333 to 17.683)**	**6.13 (4.121 to 9.107)**

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]	**60**	**58**
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/Brisbane/59/2007 (H1N1) - like strain	**100.0 (94.0 to 100.0)**	**91.4 (81.0 to 97.1)**
A/Brisbane/10/2007(H3N2) - like strain	**100.0 (94.0 to 100.0)**	**94.8 (85.6 to 98.9)**
B/Brisbane/60/2008 - like strain	**85.0 (73.4 to 92.9)**	**60.3 (46.6 to 73.0)**

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: The Frequency of Any Solicited Local Reactions. [Time Frame: During the 4 days after vaccination (Day 0 plus 3 days)]

Measure Type	Secondary
Measure Title	The Frequency of Any Solicited Local Reactions.
Measure Description	The number of participants reporting any solicited local reactions.
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.

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**
The Frequency of Any Solicited Local Reactions. [units: participants]		
Any solicited local reaction	**32**	**22**
Any induration larger than 50 mm	**1**	**2**
Any erythema	**22**	**12**
Any pain	**26**	**14**
Any ecchymosis	**5**	**4**

No statistical analysis provided for The Frequency of Any Solicited Local Reactions.

5. Secondary: The Frequency of Any Solicited Systemic Symptoms. [Time Frame: During the 4 days after vaccination (Day 0 plus 3 days)]

Measure Type	Secondary
Measure Title	The Frequency of Any Solicited Systemic Symptoms.
Measure Description	The number of participants reporting any solicited systemic symptoms.
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.

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**
The Frequency of Any Solicited Systemic Symptoms. [units: participants]		
Any solicited systemic symptom	**7**	**5**
Any temperature above 38°C for 24 hours or longer	**1**	**0**
Any chills	**6**	**2**
Any malaise	**5**	**5**

No statistical analysis provided for The Frequency of Any Solicited Systemic Symptoms.

6. Secondary: The Incidence of Any Unsolicited Adverse Events (AEs). [Time Frame: After vaccination until the end of the study; approximately 21 days]

Measure Type	Secondary
Measure Title	The Incidence of Any Unsolicited Adverse Events (AEs).
Measure Description	The number of participants reporting any unsolicited adverse events. Unsolicited adverse event (UAE) grading: Mild: Symptoms were easily tolerated and did not interfere with normal, everyday activities. Moderate: Enough discomfort to have caused some interference with normal, everyday 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.

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**
The Incidence of Any Unsolicited Adverse Events (AEs). [units: participants]		
Number of participants with at least one UAE	**25**	**21**
Number of participants reporting mild UAE	**20**	**21**
Number of participants reporting moderate UAE	**12**	**3**
Number of participants reporting severe UAE	**0**	**0**

No statistical analysis provided for The Incidence of Any Unsolicited Adverse Events (AEs).

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	The Safety Population comprised all participants who received study vaccine. 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	The Safety Population comprised all participants who received study vaccine. 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	5%

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	**14/60 (23.33%)**	**11/60 (18.33%)**
General disorders		
Injection site mass † 1		
# participants affected / at risk	**2/60 (3.33%)**	**3/60 (5.00%)**
# events	**2**	**4**
Injection site erythema † 1		
# participants affected / at risk	**2/60 (3.33%)**	**3/60 (5.00%)**
# events	**2**	**3**
Influenza like illness † 1		
# participants affected / at risk	**3/60 (5.00%)**	**0/60 (0.00%)**
# events	**3**	**0**
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	**2/60 (3.33%)**	**4/60 (6.67%)**
# events	**2**	**4**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**8/60 (13.33%)**	**4/60 (6.67%)**
# events	**10**	**5**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**3/60 (5.00%)**	**0/60 (0.00%)**
# events	**3**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

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:	NCT00888381 History of Changes
Other Study ID Numbers:	CSLCT-NHF-**09-57** 2009-011450-18 (EudraCT Number)
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Results First Received:	June 13, 2012
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