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Trial record **1 of 1** for: ASU-12-82

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# A Study to Assess the Immunogenicity and Safety of CSL's 2013/2014 Formulation of Enzira® Vaccine in Healthy Volunteers

**This study has been completed.**

**Sponsor:**
bioCSL PTY LTD

**Information provided by (Responsible Party):**
bioCSL PTY LTD

**ClinicalTrials.gov Identifier:**
NCT01857297

First received: May 12, 2013
Last updated: January 14, 2014
Last verified: January 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: November 26, 2013

| | |
|---|---|
| **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, Human |
| **Intervention:** | Biological: 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** |
|---|
| The study was non-randomized with a parallel assignment comprising of 2 groups of healthy volunteers: adults (aged 18 - 59 years) and older adults (aged 60 years or older). |

**Pre-Assignment Details**

| **Significant events and approaches for the overall study following participant enrollment, but prior to group assignment** |
|---|
| None relevant |

**Reporting Groups**

| | **Description** |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Participant Flow: Overall Study**

| | **Adults (18 to 59 Years)** | **Older Adults (60 Years or Older)** |
|---|---|---|
| **STARTED** | **60** | **60** |
| **COMPLETED** | **60** | **60** |
| **NOT COMPLETED** | **0** | **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 (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | **Adults (18 to 59 Years)** | **Older Adults (60 Years or Older)** | **Total** |
|---|---|---|---|
| **Number of Participants [units: participants]** | **60** | **60** | **120** |
| **Age, Customized [units: years] Mean (Standard Deviation)** | | | |
| **Years** | **34.5 (11.17)** | **69.4 (6.02)** | **51.9 (19.65)** |
| **Gender [units: participants]** | | | |
| **Female** | **40** | **30** | **70** |
| **Male** | **20** | **30** | **50** |

## 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 (H1N1, H3N2, and B influenza virus strains) is defined as achieving a post-vaccination titre of ≥ 40 for those participants with a pre-vaccination HI titre of < 10. A significant increase (H1N1, H3N2, and B influenza virus strains) 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 included all participants who were vaccinated with the Influenza Vaccine, provided both pre- and post-vaccination antibody titer results, did not use a prohibited medication as per the protocol, and were not excluded from the analysis according to the elimination criteria. |

**Reporting Groups**

| | **Description** |
|---|---|

| | |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Measured Values**

| | **Adults (18 to 59 Years)** | **Older Adults (60 Years or Older)** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **59** | **60** |
| **The Percentage of Evaluable Participants Achieving Seroconversion or Significant Increase in Antibody Titre. [units: percentage of participants] Number (95% Confidence Interval)** | | |
| **H1N1 strain** | **72.9 (59.7 to 83.6)** | **63.3 (49.9 to 75.4)** |
| **H3N2 strain** | **78.0 (65.3 to 87.7)** | **55.0 (41.6 to 67.9)** |
| **B strain** | **54.2 (40.8 to 67.3)** | **30.0 (18.8 to 43.2)** |

**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 (H1N1, H3N2, and B influenza virus strains) 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 included all participants who were vaccinated with the Influenza Vaccine, provided both pre- and post-vaccination antibody titer results, did not use a prohibited medication as per the protocol, and were not excluded from the analysis according to the elimination criteria. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Measured Values**

| | **Adults (18 to 59 Years)** | **Older Adults (60 Years or Older)** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **59** | **60** |
| **The Geometric Mean Fold Increase (GMFI) in Antibody Titre After Vaccination. [units: fold increase] Geometric Mean (Standard Deviation)** | | |

| | | |
|---|---|---|
| **H1N1 strain** | **12.90 (4.764)** | **6.11 (3.675)** |
| **H3N2 strain** | **17.85 (5.237)** | **5.77 (4.549)** |
| **B strain** | **5.30 (3.522)** | **2.81 (2.858)** |

**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** | For the H1N1, H3N2 and B influenza virus strains. Note: No SRH data were collected. |
| **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 included all participants who were vaccinated with the Influenza Vaccine, provided both pre- and post-vaccination antibody titer results, did not use a prohibited medication as per the protocol, and were not excluded from the analysis according to the elimination criteria. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Measured Values**

| | **Adults (18 to 59 Years)** | **Older Adults (60 Years or Older)** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **59** | **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)** | | |
| **H1N1 strain** | **98.3 (90.9 to 100)** | **95.0 (86.1 to 99.0)** |
| **H3N2 strain** | **100 (93.9 to 100)** | **98.3 (91.1 to 100)** |
| **B strain** | **86.4 (75.0 to 94.0)** | **51.7 (38.4 to 64.8)** |

**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 percentage 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 included all participants who received the Influenza Vaccine and provided follow-up safety data. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Measured Values**

| | **Adults (18 to 59 Years)** | **Older Adults (60 Years or Older)** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **60** | **60** |
| **Frequency of Any Solicited Adverse Events (AEs) [units: percentage of participants]** | | |
| **Any solicited local AE** | **61.7** | **13.3** |
| **Induration > 50 mm** | **1.7** | **0** |
| **Erythema** | **5.0** | **0** |
| **Ecchymosis** | **3.3** | **0** |
| **Pain** | **58.3** | **13.3** |
| **Any solicited systemic AE** | **25** | **10** |
| **Temperature > 38°C for ≥ 24 hours** | **0** | **1.7** |
| **Chills** | **10** | **6.7** |
| **Malaise** | **23.3** | **6.7** |

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

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

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Frequency of Any Unsolicited AEs |
| **Measure Description** | The percentage of participants reporting any unsolicited AEs. Unsolicited AEs include AEs other than those specifically solicited. |
| **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 included all participants who received the Influenza Vaccine and provided follow-up safety data. |

**Reporting Groups**

| | **Description** |
|---|---|

| | |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Measured Values**

| | Adults (18 to 59 Years) | Older Adults (60 Years or Older) |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **60** | **60** |
| **Frequency of Any Unsolicited AEs [units: percentage of participants]** | **46.7** | **36.7** |

**No statistical analysis provided for Frequency of Any Unsolicited AEs**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | For solicited AEs: During the 4 days after vaccination (Day 0 plus 3 days); For unsolicited AEs and serious AEs (SAEs): After vaccination until the end of the study (approximately 21 days). |
| **Additional Description** | The other AEs presented include solicited and unsolicited AEs. The Safety Population included all participants who received CSL Influenza Vaccine and provided follow-up safety data. |

**Reporting Groups**

| | Description |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Serious Adverse Events**

| | Adults (18 to 59 Years) | Older Adults (60 Years or Older) |
|---|---|---|
| **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** | For solicited AEs: During the 4 days after vaccination (Day 0 plus 3 days); For unsolicited AEs and serious AEs (SAEs): After vaccination until the end of the study (approximately 21 days). |
| **Additional Description** | The other AEs presented include solicited and unsolicited AEs. The Safety Population included all participants who received CSL Influenza Vaccine and provided follow-up safety data. |

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5% |

**Reporting Groups**

| | Description |
|---|---|
| **Adults (18 to 59 Years)** | Healthy volunteers aged 18 to 59 years received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |
| **Older Adults (60 Years or Older)** | Healthy volunteers aged 60 years or older received a single 0.5 mL dose of CSL Influenza Vaccine by intramuscular or subcutaneous injection. |

**Other Adverse Events**

| | Adults (18 to 59 Years) | Older Adults (60 Years or Older) |
|---|---|---|
| **Total, other (not including serious) adverse events** | | |
| **# participants affected / at risk** | **40/60 (66.67%)** | **16/60 (26.67%)** |
| **General disorders** | | |
| **Injection site pain † 1** | | |
| **# participants affected / at risk** | **35/60 (58.33%)** | **8/60 (13.33%)** |
| **# events** | **35** | **8** |
| **Malaise † 1** | | |
| **# participants affected / at risk** | **14/60 (23.33%)** | **4/60 (6.67%)** |
| **# events** | **15** | **5** |
| **Chills † 1** | | |
| **# participants affected / at risk** | **6/60 (10.00%)** | **4/60 (6.67%)** |
| **# events** | **7** | **5** |
| **Pyrexia * 1 [4]** | | |
| **# participants affected / at risk** | **4/60 (6.67%)** | **0/60 (0.00%)** |
| **# events** | **4** | **0** |
| **Nervous system disorders** | | |
| **Headache * 1 [4]** | | |
| **# participants affected / at risk** | **15/60 (25.00%)** | **6/60 (10.00%)** |
| **# events** | **17** | **6** |
| **Respiratory, thoracic and mediastinal disorders** | | |
| **Oropharyngeal pain * 1 [4]** | | |
| **# participants affected / at risk** | **6/60 (10.00%)** | **1/60 (1.67%)** |
| **# events** | **7** | **1** |

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 16
[4] unsolicited adverse event

## 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:<br>☐ 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.<br>☐ 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.<br>☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.<br>**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: bioCSL, Head of Clinical Operations
Organization: bioCSL PTY LTD
phone: csl.clinicaltrials@csl.com.au
e-mail: csl.clinicaltrials@csl.com.au

**No publications provided**

| | |
|---|---|
| Responsible Party: | bioCSL PTY LTD |
| ClinicalTrials.gov Identifier: | NCT01857297 History of Changes |
| Other Study ID Numbers: | CSLCT-**ASU-12-82**<br>2013-000945-37 ( EudraCT Number ) |
| Study First Received: | May 12, 2013 |
| Results First Received: | November 26, 2013 |
| Last Updated: | January 14, 2014 |
| Health Authority: | United Kingdom: Medicines and Healthcare Products Regulatory Agency |