

Zofran Trial Study

Coastal Valleys EMS Regional ALS Providers will participate in a trial study of the drug Zofran (Ondansetron).

During this study, each case where Zofran was used will be audited to determine if the decision by the paramedic to administer Zofran was correct and what effect the drug had on the patient.

This will require paramedics to fill out an evaluation form each time Zofran is administered. Provider Agency CQI staff will audit these calls, then will submit them to the EMS agency. The EMS Agency will review these calls then submit them to the State of California EMS authority.

This will be done on a monthly basis throughout the study.

The Coastal Valleys EMS Agency is one of the first in California to do a trial study of Zofran.

What is Zofran?

- The generic name is Ondansetron
- Zofran blocks the actions of chemicals in the body that can trigger nausea and vomiting (N/V).
- Zofran is used to prevent nausea and vomiting.
- Zofran has been primarily used to prevent N/V in cancer patients.

What is Zofran?

- Zofran is a serotonin 5-HT₃ receptor antagonist.
- Its effects are on both the peripheral and central nerves.
- One part is to reduce the activity of the vagus nerve. The vagus nerve activates the vomiting center in the medulla oblongata.
- The other is a blockage of serotonin receptors in the chemoreceptor trigger zone.
- Zofran does NOT have an effect on the dopamine or muscarinic receptors.

The History of Zofran

- Zofran, or Ondansetron was developed around 1984 by scientists working at Glaxo's laboratories in London.
- The FDA approved of its use in the USA in 1991.

Zofran's Effects on Diseases

- Schizophrenia: A 2006 trial indicated that Zofran may have value in the treatment of schizophrenia, as an adjunct to haloperidol.
- Parkinson's: Studies have indicated that Zofran may be a possible treatment for psychosis resulting from advanced Parkinson's disease.
- Alcoholism: Zofran has been found to lower the cravings for alcohol, especially in early onset alcoholics.

Adverse Effects

- Zofran is a well tolerated drug with few side effects.
- Headache, constipation and dizziness are the most common.
- There have been no significant drug interactions reported with Zofran.
- Unusual but possible side effects include: fatigue, diarrhea and blurred vision.
- Zofran is safe for use in pregnancy

Zofran Protocol

- Indications: Prevention and control of nausea and vomiting in adults and pediatrics.
- Precautions: Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other 5HT₃ receptor antagonists (i.e., dolasetron (Anzemet) and granisetron (Kytril)).

Zofran Protocol

- How Supplied: 2mg/ml in 2 ml vial (total = 4mg), 4mg orally dissolvable tablets
- Age Range: 4 years or greater
- Indication:
 - Intractable vomiting
 - Severe nausea
- Dose: 4mg slowly given (over 30 seconds)
- Route: IV, IM, PO dissolvable tablet
- Special: Consider other treatable causes.

Zofran Protocol

- Unlike other anti-emetics, Zofran typically doesn't cause sedation.
- Peak plasma concentrations of the drug occur 10 minutes after IV doses, and 40 minutes after IM injection.
- Both routes have the same mean elimination half-life of four hours.

Ondansetron Trial Study Continuous Quality Improvement Form

■ Part I: To be completed by treating paramedic after every Zofran administration

■ Date: ___/___/___ Incident #: _____
 ■ Call Type (circle): 911 Inter-facility Transport Other
 ■ Paramedic: _____ Unit: _____ Base Hosp: _____
 ■ Pt Age: _____ Sex/Gender: _____ Chief Complaint: _____
 ■ Indication (circle): Vomiting Severe Nausea Other: _____
 ■ # doses given: _____ Distress prior: MODERATE SEVERE
 ■ Dose #1: _____ mg Route: IV IM PO Effect: _____
 ■ Dose #2: _____ mg Route: IV IM PO Effect: _____
 ■ Comments: _____

■ Part II: To be completed by Provider CQI Coordinator

■ Reviewed by: _____ Date: ___/___/___
 ■ Use indicated by protocol? Y N Explain: _____
 ■ VS prior and after each dose? Y N Explain: _____
 ■ Correct dose? Y N Explain: _____
 ■ Correct route? Y N Explain: _____
 ■ Effect documented? Y N Explain: _____
 ■ Any adverse effects? Y N Explain: _____
 ■ Comments: _____

■ Part III: To be completed by CVEMSA Agency CQI Coordinator

■ Reviewed by: _____ Date: _____
 ■ Use indicated by protocol? Y N Explain: _____
 ■ All documentation completed? Y N
 ■ Agree with Provider CQI Coordinator? Y N
 ■ Comments: _____

Medical Director comments: _____

Coastal Valleys EMS Agency

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Zofran Clinical Testing

- All paramedics must pass a written exam
- No paramedic may use Zofran until he/she has successfully passed the written test and has been authorized to participate in the study by their Provider Agency.

Participation in the study

- Once a paramedic has received approval to participate in the study, they will be required to fill out and submit an evaluation form each time Zofran is used.
- The CQI forms shall be submitted to the designated QI contact at the conclusion of each shift.

Participation in the study

- Provider Agency CQI staff will review each call where Zofran was used along with each call with a chief complaint of N/V.
- At the end of each month, The Provider Agency QI Coordinator will forward all documents to the EMS agency.
- It is anticipated that this study will be for a period of not less than 180 days