Gardasil ® (Human papillomavirus quadrivalent recombinant vaccine)

Adverse Effects

The Gardasil® vaccine is composed of virus-like particles made from purified protein of the outer coating of the four most common strains of human papillomavirus (HPV); the vaccine protein is indistinguishable from HPV but lacks viral DNA and is therefore noninfectious.[1, 2, 4, 5, 14] When it is injected intramuscularly, the vaccine induces immunity without causing infection.[14]

The vaccine is well tolerated; it has been tested in more than 21 000 females ages16 to 26 worldwide. Subjects in clinical trials were followed for an average of two years in Phase III studies and up to five years in Phase II trials.[2] Studies have shown no serious side effects attributed to the vaccine.[14] The most common side effects include injection site pain, itching, rash, redness, swelling at the injection site, headache, nausea, muscle pain, dizziness, and mild to moderate fever.[1,2,6,7,10,13,14] Adverse reactions led to discontinuation of the vaccine course (three injections at months 0,2, & 6) in less than 0.1% of subjects.[2,4] No reported deaths have been linked to the vaccine (reported deaths of study subjects were most commonly due to traffic accidents).[2,6,10]

The Females United to Unilaterally Reduce Endo/Ectocervical Disease (FUTURE) I study, an ongoing, double-blind, placebo-controlled, randomized trial sponsored by Merck, enrolled 5455 subjects. Vaccine recipients were more likely than placebo recipients to have adverse events at the injection site (87% vs. 77%), the most common being injection site pain.[11]

The vaccine is not recommended for use in women known to be pregnant.[13] If a woman finds out she is pregnant after she has started the three-dose vaccine series, she should wait until after the pregnancy to finish the series. [14] Among inadvertent pregnancies during the study period, but more than thirty days after any vaccination, rates of spontaneous abortion and congenital abnormalities were similar to background levels and there was no significant difference in rates between the vaccine and placebo groups.[3,6,12] Among women who conceived within thirty days of vaccination, there were five cases of congenital anomalies in infants born to mothers who received Gardasil and none in infants born to mothers in the placebo group. The five diverse anomalies included the following: hip dysplasia, ankyloglossia with pyloric stenosis, congenital hydronephrosis, congenital megacolon, and club foot.[6] A review by an external specialist who was unaware of study-group assignments concluded that all reported anomalies were diverse and consistent with those generally seen in young women.[12]

There were a higher proportion of cases of respiratory illnesses and gastroenteritis among infants of mothers who were administered Gardasil during the time they were breastfeeding. The package insert includes a cautionary statement about use of Gardasil in women who are breastfeeding.[6]

Conclusion

Gardasil® is safe to use in women who are not pregnant or breastfeeding. No serious adverse events have been reported. More common, less serious side effects were mainly due to injection and were similar to those reactions seen with other vaccines. It is safe for a woman to become pregnant once she has completed the vaccination series,

however, women should refrain from becoming pregnant during the vaccination series and should delay vaccination should they become pregnant within that time period.

For more information about Gardasil® please see www.stueckpharmacy.com.

References

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