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Vaccination against hepatitis B among prisoners in Iran: Accelerated vs. classic vaccination

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ABSTRACT

Background: Prisoners and injecting drug users are at constant risk of hepatitis B virus (HBV) infection and the classic 6-months HBV vaccination might not provide immunization rapidly enough. In this randomized clinical trial we investigated the efficacy of an accelerated vaccination protocol vs. classic schedule among prisoners in Iran.
Methods: 180 prisoners were randomized into 2 vaccination groups; group A underwent accelerated vaccination at 0, 1, 4 and 8 weeks and group C were vaccinated at 0, 1 and 6 months. Antibody against Hepatitis-B surface-antigen (anti-HBs) was assessed at baseline, one, two, six and eight months after the first vaccine dose using immunoenzymatic assays. Seroprotection was defined as anti-HBs titer of 10 IU/L or more. Anti-HBc and HBsAg were measured at baseline and 8th month to evaluate new HBV infection and failure of vaccination.
Results: Overall compliance was 100% and 90.4% in groups A and C respectively. While seroprotection rate at one month was significantly higher in group A (22.4%) compared to group C (4.7%), in the 8th month 78.8% and 93.4% seroprotection was achieved in groups A and C respectively ($P < 0.002$).
Conclusion: Compared to classic HBV vaccination regimen, an accelerated 0, 1, 4 and 8 weeks vaccination schedule can achieve early seroprotection more rapidly, provides clinically sufficient seroprotection with higher compliance in prisoners and can be suggested in situations that rapid immunization against HBV infection is warranted.

1. Introduction

Hepatitis B virus (HBV) infection is one of the most common causes of acute and chronic hepatitis worldwide and poses a great burden on health systems [1–3]. Chronic infections with HBV might lead to development of hepatocellular carcinoma (HCC), cirrhosis and death [4]. Based on reports by World Health Organization (WHO), it is estimated that annually over 5 million new cases of HBV infection will emerge worldwide and 500,000–1,200,000 deaths will occur due to HBV related complications [5,6].

Mass HBV vaccination program for newborns was implemented in Iran in 1993 leading to dramatic decline in prevalence of HBV infection from 7.2% in 1979 to 2.14%

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in last 5 years [7]. Additionally, a "Nationwide HBV vaccination program for 17 year-old adolescents" has been recently implemented throughout Iran targeting those who were not included in the 1993 mass vaccination program along with 1989–1992-born teenagers [8].

HBV infection is a major health concern in Iran and two decades after start of mass vaccination programs, it still counts as a considerable cause of chronic liver disease in Iran with an estimated HBsAg prevalence of 2.6% [9].

Although nationwide vaccination of children against HBV has proven its efficacy, yet there are several high-risk adult groups that remain vulnerable and prison inmates are among the high risk groups for HBV infection [10,11]. The cause is largely attributed to prisoners' social and behavioral characteristics such as intravenous drug injections or tattooing [11].

Higher incidence of HBV infection has been observed in prisoners with history of injecting drug use compared to those with no such history. Additionally history of injection and needle sharing is significantly associated with HBV infection in prisoners [11].

An investigation by Center for Disease Control and Prevention (CDC) in USA indicated that almost 16% of new HBV cases are injecting drug users and the incidence of HBV infection in this group is estimated to be 10–31 cases per 100 person-years which is significantly higher than overall incidence in general population [12].

Furthermore another report by CDC in USA revealed that almost 30% of those diagnosed with HBV infections have history of imprisonment most of which had also history of injection [13]. Another investigation in Brazilian prisoners estimated the prevalence of HBV infection to be 17.9% with 0.5% carrier rate [14].

Up to our knowledge, there are a few reports on the current status of HBV infection among prisoners in Iran. A recently published investigation has demonstrated that approximately 5.8% of IV drug users in detention in Iran are HBsAg positive and another study in 2003 estimated the prevalence of HBV infection to be 3.8% in prisons [15,16].

Altogether the current status of HBV infection in correctional facilities highlights the need for targeting prisoners for vaccination against HBV.

However classic HBV vaccination schedule (3 doses at 0, 1 and 6 months) might not be applicable to all inmates as they either might be released anytime during this 6-month period or as well develop HBV infections due to high-risk behaviors before achieving proper seroprotection.

Currently different accelerated vaccination protocols have been proposed for HBV vaccination including a 0, 1 and 2 months vaccination regimen and a 0, 1 and 3 week vaccination regimen to name a few [17,18]. Considering prisoners' high risk environment, the efficacy of these protocols on providing sufficient seroprotection along with acceptable compliance in prisoners is to be tested.

In this randomized trial we aim to compare an accelerated HBV vaccination protocol with the classic schedule regarding their efficacy in providing sufficient seroprotection in prisoners in Shiraz, Iran.

2. Materials and methods

2.1. Subjects and samples

This parallel-group randomized clinical trial was performed from June 2006 to July 2007 in Shiraz, the capital of Fars province in southern Iran in a one-year period. A total of 250 subjects were primarily assessed for eligibility to be recruited from 3 prisons and correctional facilities inside Shiraz. Cluster sampling and systematic sampling methods were used to select individuals. The subjects were then informed of the purpose and methods of the investigation and a written consent was obtained from each individual. Subjects were also informed of their anonymity and their right to quit the study at anytime during the process. Those unwilling to participate were eliminated and eventually 180 individuals consented to participate in the study.

The protocol for the research project was approved by Shiraz University of Medical Sciences Ethic Committee. Moreover the protocol design and report is consistent with consolidated standards of reporting trials (CONSORT) statement [19]. Fig. 1 demonstrates the recruitment and randomization process.

A standard questionnaire was designed and expert physicians interviewed prisoners regarding their demo-

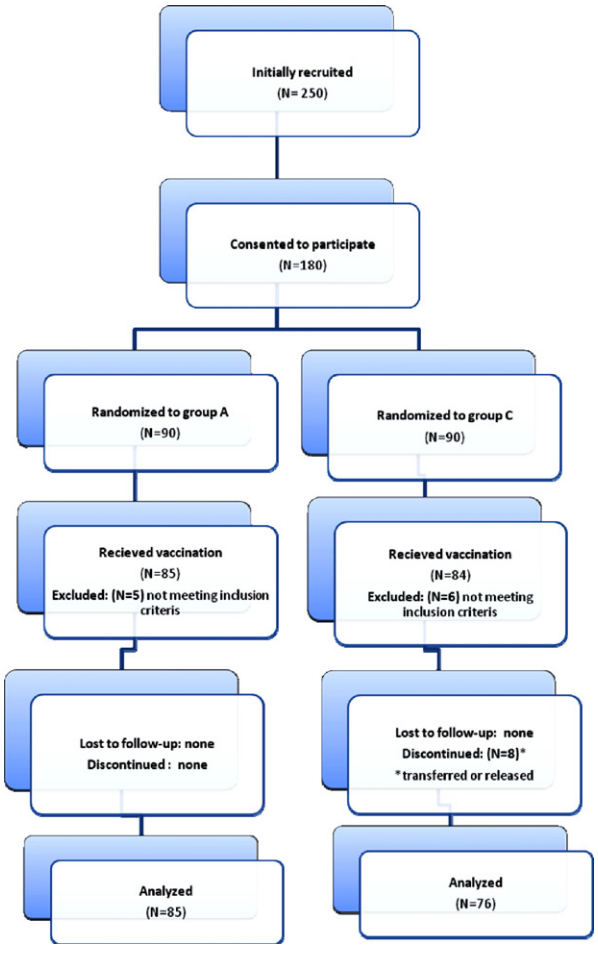

Fig. 1. Overview of participants' recruitment and randomization process.