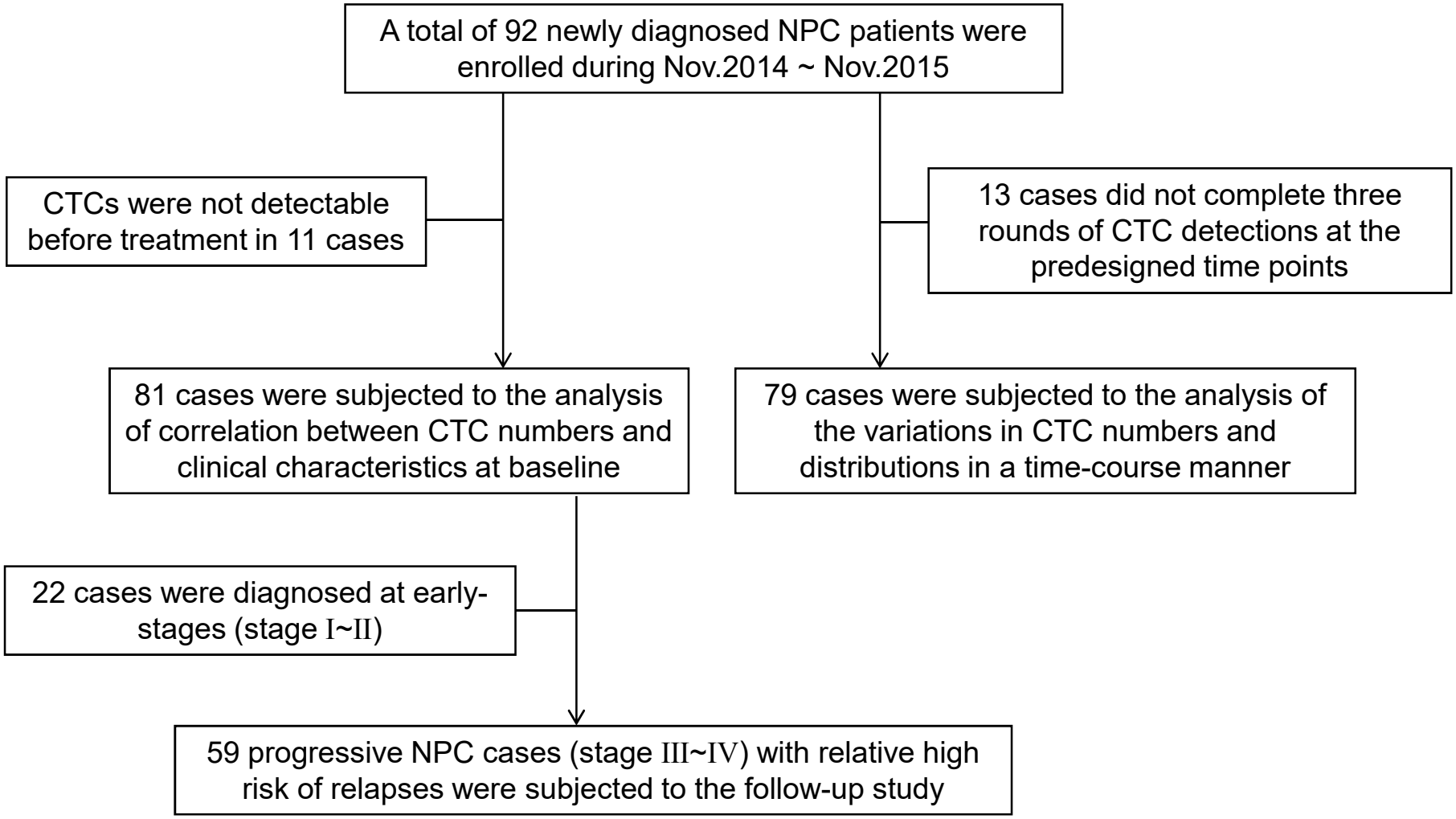# Study Design and Enrollment