

1. iStent 삽입술 대 약물치료군: 2개 연구(3편 문헌)

연번(Ref ID)		7(10976), 8(10450)
1저자(출판연도)		Vold(2016), Fechtner(2019)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Eyes were randomized within a non-blocked computergenerated, <u>concealed</u> 1:1 random allocation sequence
Allocation concealment (배정순서 은폐)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-The sealed, unlabeled randomization envelope was opened at the conclusion of the screening visit if the subject qualified for study participation. -The allocation sequence was produced by the study sponsor (Glaukos Corporation)
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-randomized in a 1:1 ratio under an open-label, <u>unmasked</u> strategy
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	결과에 영향을 미치지 않을 것으로 판단함 추적관찰 결측이 두 군간 유사하게 발생하였음 -Reasons for study discontinuation included loss to follow-up (2 and 4 subjects in the stent and travoprost groups, respectively), death unrelated to study (2 and 1 subject, respectively), investigator discretion (1 stent subject), and moving out of the country (1 travoprost subject).
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-The study protocol had prespecified primary and secondary efficacy end points at 12 and 24 months, with planned extension through 5 years to gather long-term safety and efficacy data -NCT01443988, clinicaltrials.gov
Other bias : Funding (그 외 비뚤림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Grant support - Research to Prevent Blindness -Operational and financial support for completion of this study, writing assistance in manuscript preparation, and article processing charges were provided by Glaukos Corporation, San Clemente, California.

연번(Ref ID)		5(11171)
1저자(출판연도)		Fea(2014)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	'무작위' 외에 추가기술이 없음 - Subjects were then randomized
Allocation concealment (배정순서 은폐)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	참여자(229명) 중 최종 연구대상자(192명)은 배제기준에 따라 선정되었고, 연구대상자에 대해 무작위 배정을 실시하였음. 연구대상자에 대한 결측보고는 없었기 때문에 결과에 영향을 끼치지 않은 것으로 판단함 -with a nonresponder assumption for missing data
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	안전성과 효과성을 모두 보고하였음
Other bias : Funding (그 외 비뚤림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Glaukos Corporation provided study devices, sponsorship for performing this study -Dr Fea received financial support from Glaukos

2. iStent삽입술과 백내장수술 병용군 대 백내장수술 단독군: 5개 연구(8편 문헌)

연번(Ref ID)		3(11199), 4(9960)
1저자(출판연도)		Samuelson(2011), Craven(2012)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음 -Patients were randomized into 1 of 2 treatment groups: stent implantation in conjunction with cataract surgery (treatment group) or cataract surgery alone (control group).
Allocation concealment (배정순서 은폐)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-prospective, randomized, open-label, multicenter, controlled US Investigational Device Exemption clinical trial
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	눈가림이 시행되지 않았으나, 눈가림이 결과평가에 미치지 않음 -However, although the procedure was not masked, there is no way to see or identify the iStent at the slit lamp without gonioscopy; thus, the <u>examiner was unable to tell</u> to which group the patient belonged at the time of tonometry.
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	중재군 19명, 대조군 22명 탈락, 결과에 영향을 미치지 않을 것으로 판단함 ITT 분석을 수행하여 결과에 영향을 끼치지 않음 -the intent-to-treat population using a last-observation-carried-forward approach.
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	프로토콜 언급은 있으나, 구체적으로 기술되어 있지 않음. 단, 연구방법에 언급된 모든 결과를 보고 하고 있음 -The protocol was amended in July 2007 -This study was registered with clinicaltrials.gov as NCT00323284
Other bias : Funding (그 외 비뚤림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	Funding: Glaukos Corp.

연번(Ref ID)		9(11182), 11(11515)
1저자(출판연도)		Samuelson(2019), Singh(2021)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-The randomization scheme was based on a <u>computer-generated list</u> .
Allocation concealment (배정순서 은폐)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-prospective, randomized, <u>single-masked</u> , controlled, multicenter U.S. pivotal trial
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-After surgery, <u>subjects and the technicians performing postoperative measurements were masked</u> to treatment assignment for the duration of study follow-up.
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	ITT 분석을 수행하여 결과에 영향을 끼치지 않음 -Effectiveness outcomes also were analyzed for the <u>intent-to-treat cohort</u> , consisting of all randomized subjects. Safety outcomes were assessed within the Safety Population, which consisted of all randomized subjects, with analysis based on the treatment actually received.
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	프로토콜 언급은 있으나, 구체적으로 기술되어 있지 않음. 단, 연구방법에 언급된 모든 결과를 보고 하고 있음 -This study was registered with clinicaltrials.gov as NCT00323284
Other bias : Funding (그 외 비뚤림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	Funding: Glaukos Corp.

연번(Ref ID)		10(10304)
1저자(출판연도)		Kozera(2021)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	무작위 배정방법에 대해 제시하였음 -A computer-generated randomization list was created for this study, with allocation concealment implementation.
Allocation concealment (배정순서 은폐)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Randomization was performed using sealed envelopes, opened on the day of surgery, to determine the randomization group. -Eyes were individually randomized in a 1:1 ratio
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음 prospective, randomized, single-center trial
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	결측에 대한 정보는 제시되어 있지 않으나, 최종 대상자수에 대한 결측치는 없었음
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	프로토콜 언급은 있으나, 구체적으로 기술되어 있지 않음. 단, 연구방법에 언급된 모든 결과를 보고 하고 있음 -The study was registered at ClinicalTrials.gov under the number NCT03807869
Other bias : Funding (그 외 비뚤림)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	The authors did not receive any funding.

연번(Ref ID)		1(10459)
1저자(출판연도)		Fernandez-Barrientos(2010)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	무작위 배정순서에 대한 추가 기술이 없음 -Eligible patients were randomly assigned
Allocation concealment (배정순서 은폐)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	-prospective, randomized, clinical study
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	참여자 중 연구참여를 거부한 사람을 제외하고, 각 군에 할당되었으며 최종 연구대상자에 대한 결측치는 없었음
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	프로토콜 언급은 있으나, 구체적으로 기술되어 있지 않음. 단, 연구방법에 언급된 모든 결과를 보고 하고 있음 -ClinicalTrials.gov number, NCT00326066
Other bias : Funding (그 외 비뚤림)	<input type="checkbox"/> 낮음 <input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 불확실	Supported by Glaukos Corporation

연번(Ref ID)		2(11096), 6(10814)
1저자(출판연도)		Fea(2010), Fea(2015)
영역	비뚫림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Patient randomization was generated with a 2:1 ratio using Stata data analysis and <u>statistical software</u> (version 10, StataCorp LP).
Allocation concealment (배정순서 은폐)	<input type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 불확실	언급없음
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Patients were <u>masked</u> to their assignment, as were staff members who measured IOP throughout the study. -Investigators were <u>masked</u> to treatment assignment when measuring IOP and when determining when or whether to add medications.
Blinding of outcome assessment (결과평가에 대한 눈가림)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-Examinations at 6 months and 12 months included gonioscopy by an operator <u>unaware</u> of the treatment assignment.
Incomplete outcome data addressed (불충분한 결과자료)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	추적손실에 대한 기술이 제시되어 있으며, 결과에 영향을 끼치지 않을 것으로 판단됨 -Three patients, all in the control group, were lost to follow-up. One patient had a capsule rupture, 1 did not present for the 6-month scheduled visit, and 1 died. -she subsequently died from complications from the ankle surgery.
Free of selective reporting (선택적 보고)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	프로토콜 언급은 있으나, 구체적으로 기술되어 있지 않음. 단, 연구방법에 언급된 모든 결과를 보고 하고 있음 -This trial is registered with: NCT00847158
Other bias : Funding (그 외 비뚫림)	<input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 높음 <input type="checkbox"/> 불확실	-The author has no financial or proprietary interest in any material or method mentioned. -The authors declare that they have no conflict of interests.